“PROSPECTIVE RANDOMISED STUDY TO COMPARE CLASSIC-LMA AND I-GEL IN ANAESTHETISED SPONTANEOUSLY BREATHING PATIENT UNDERGOING MINOR GYNAECOLOGICAL SURGERIES”

Dissertation submitted to

THE TAMILNADU DR. M.G.R.MEDICAL UNIVERSITY

in partial fulfilment for the award of the Degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

BRANCH X

INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE

MADRAS MEDICAL COLLEGE

CHENNAI- 600 003.

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CERTIFICATE

This is to certify that the dissertation entitled, **" Prospective randomised study to compare classic- LMA and I-gel in anaesthetised spontaneously breathing patient undergoing minor gynaecological surgeries "** submitted by **Dr.A.RAJENDRAN**, in partial fulfilment for the Degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai., is a bona fide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College and Government Hospital, during the academic year 2012-2015.

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This is to certify that the dissertation entitled, **" Prospective randomised study to compare classic- LMA and I-gel in anaesthetised spontaneously breathing patient undergoing minor gynaecological surgeries ",** in partial fulfilment for the Degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai., is a bona fide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College and Government Hospital, during the academic year 2012-2015.

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DECLARATION

I, **Dr.A.RAJENDRAN**, solemnly declare that this dissertation entitled **"Prospective randomised study to compare classic-LMA and I-gel in anaesthetised spontaneously breathing patient undergoing minor gynaecological surgeries"** is a bona fide work done by me in the Institute of Anaesthesiology and Critical Care, Madras Medical College and Government General hospital, Chennai, during the period 2012 to 2015 under the guidance of **Prof. Dr.B.KALA, M.D.,D.A.**, Director, Institute of Anaesthesiology and Critical Care, Madras Medical College and Government General Hospital, Chennai – 3 and submitted to **The Tamilnadu Dr. MGR Medical University,** Guindy, Chennai – 32, in the partial fulfillment of the requirements for the award of the degree of MD Anaesthesiology (Branch X).

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LIST OF ABBREVIATONS

ASA	-	American Society of Anaesthesiologists
BPM	-	Beats per minute
BZD	-	Benzo diazepam
cm H_2O	-	Centimeters of Water
$CMRO_2$	-	Cerebral metabolic rate of oxygen
cl^-	-	Chloride channels
CNS	-	Central nervous system
CO_2	-	Carbon dioxide
COPD	-	Chronic obstructive pulmonary disease
c-LMA	-	Classic laryngeal mask airway
CPAP	-	Continuous positive airway pressure
DBP	-	Diastolic Blood Pressure
EEG	-	Electro Encephalo Graphy
ET	-	Endo tracheal Tube
GABA	-	Gamma-amino butyric acid
HR	-	Heart rate
hrs	-	Hours
im	-	Intra muscular
IV	-	Intra venous
IPPV	-	Intermittent positive pressure ventilation
Kg	-	Kilogram
KOH	-	Potassium hydroxide
LMA	-	Laryngeal mask airway

MAC	-	Minimum alveolar concentration
MAP	-	Mean Arterial Pressure
µg	-	Micrograms
Mg	-	Milligrams
ml	-	Milliliters
mins	-	Minutes
mmHg	-	Millimeter of mercury
%	-	Percentage
$PaCO_2$	-	Partial pressure of carbon dioxide in blood
PLMA	-	Proseal laryngeal mask airway
Secs	-	Seconds
SAD	-	Supraglottic airway device
SBP	-	Systolic Blood Pressure
SVR	-	Systemic vascular resistance

"PROSPECTIVE RANDOMISED STUDY TO COMPARE CLASSIC-LMA AND I-GEL IN ANAESTHETISED SPONTANEOUSLY BREATHING PATIENT UNDERGOING MINOR GYNAECOLOGICAL SURGERIES"

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ABSTRACT

BACKGROUND AND OBJECTIVES

Maintenance of airway is an integral part of general anaesthesia. Various airway devices are used for this purpose. Hemodynamic changes are major hazards of general anaesthesia with endotracheal intubation and are probably generated by direct laryngoscopy and endotracheal intubation.

Supraglottic airway devices have been widely used as an alternative to tracheal intubation during general anaesthesia. Laryngeal mask airway is a Supraglottic airway device with an inflatable cuff forming a low pressure seal around the laryngeal inlet and permitting ventilation .The I-gel is a novel Supraglottic airway device made of thermoplastic elastomer which is soft gel like and transparent. It does not have an inflatable cuff.

In view of this, the present study was undertaken to compare the performance of two Supraglottic airway devices classic Laryngeal Mask Airway and I-gel in anaesthetised spontaneously breathing patient undergoing Elective minor gynaecological surgeries under general anaesthesia.

METHODOLOGY

Eighty patients scheduled for various elective minor gynaecological surgeries, under general anaesthesia who meet the inclusion criteria were included in these study and were randomly divided into two groups with 40 patients in each group. In group I classical LMA was used and in group II , I-gel was used. Both the devices were compared in relation to the ease of insertion, number of insertion attempts, time of insertion, airway leak pressure, gastric insufflation, hemodynamic changes, intra and postoperative complications.

RESULTS

There was no statistically significant difference between the devices with respect to ease of insertion, number of attempts of insertion. Gastric insufflation. The mean time of insertion for I-gel was 22.82±4.30 seconds which was significantly shorter compared to c LMA with mean insertion time of 25.88±4.32 seconds (P = 0.002). The mean airway leak pressure with I-gel was significantly higher as compared with c LMA (23.82±2.47 and 19.12±2.23 cm H_2O, respectively p=0.00). There were no statistically significant differences in hemodynamic changes and postoperative complication between the devices.

INTERPRETATION AND CONCLUSION

Both I-gel and classic LMA are easy to insert and provide an effective airway during spontaneously breathing patients under general anaesthesia. But insertion of I-gel was easier and more rapid than insertion of c-LMA and also I-gel providing a better airway sealing pressure as compared to c-LMA.

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5.	MASTER CHART

INTRODUCTION

INTRODUCTION

The supraglottic airway device is a novel device, which fills the gap in airway management between tracheal intubation and use of face mask. Dr.Archie Brain, a british anaesthesiologist, for the first time introduced the laryngeal mask airway in 1983, designed to be positioned around the laryngeal inlet that could overcome the complication associated with endotracheal intubation and yet, be simple and atraumatic to insert[24]. Careful observations and clinical experience have lead to several refinement of Brain's original prototype leading to development of newer supraglottic airway devices with better features for airway maintenance[24]. These airway devices can be grouped in to (i) intraglottic (ii) extraglottic. As time went on , additional devices were added to the LMA family to satisfy specific needs and a number of other devices were developed. There are a large number of supraglottic airway devices, some of which appear similar to the LMA family and others that work under a different concept[35].

When intubation is done with help of laryngoscopy ,there will be stimulation of sympathetic system result in adverse events in the form of raised heart rate, increased arterial pressure ,dysrhythmias ,increased tension in cranial cavity . These adverse events are well tolerated by healthy individuals, but in high risk peoples like hypertensive, ischemic heart disease patients, cerebro vascular insufficient persons may be harmful.[22]. This laryngoscopic reaction in such

individuals may predispose to development of pulmonary edema, myocardial insufficiency and cerebrovascular accident[8,25]. Supraglottic airways can be used in surgery which are done under general anaesthesia in order to avoid these complications. The gold standard supra glottis airway devices is LMA –classic. It was used in practice since 1983 .

The laryngeal mask airway is a supraglottic airway device with an inflatable cuff which produces a low pressure seal around the inlet of larynx and helping ventilation[24]. The I- gel is a new one which is also supraglottic airway .It does not have inflatable cuff . Instead of cuff it has soft gel like material which is transparent thermo softening plastic. There will be a separate port for Ryles tube insertion. [7] When compared to endotracheal intubation these devices will not give protection to lungs from aspirated food particles completely. These laryngeal mask airway carries 0.002% aspiration risk .This is equal to endotracheal ventilation in elective patients[21].

The newer supraglottic airway device, I-gel was introduced by Dr. Muhamad Aslam Nasir in 2007. The advantages of I-gel are insertion is easy , tissue compression is minimal , and an inbuilt biteblock[17].

Many studies have been done to compare I-gel with Proseal LMA. But not many studies have been done to compare the clinical uses of the two supraglottic

airway devices namely I-gel and classical LMA. Hence, this study was undertaken in Institute of Obstetrics and Gynecology, Rajiv Gandhi Government General Hospital, Chennai during the period August 2014 to September 2014. In this study, we compare these two supraglottic `airway devices in relation to ease of insertion, number of insertion attempts, time for insertion, airway leak pressure, hemodynamic changes, intra and postoperative complications in anaesthetized spontaneously breathing patients undergoing elective minor gynaecological surgeries under general anaesthesia.

AIM AND OBJECTIVES OF THE STUDY

AIM & OBJECTIVES

AIM:

A Prospective Randomized control study to compare the two supraglottic airway devices classic -LMA and I-gel in anaesthetized spontaneously breathing adult patients posted for minor gynaecological surgeries under general anaesthesia at Institute of Obstetrics and Gynecology (MMC, Chennai).

Primary objectives:

1) Ease of insertion
2) Time taken for insertion
3) Number of insertion attempts
4) Leak pressure
5) Gastric insufflation
6) Hemodynamic parameters

Secondary objectives:

Adverse events:

- Lip, tongue, dental injuries
- Post operative hoarseness of voice, dysphagia, sore throat.

BASIC ANATOMY

BASIC ANATOMY [33,34,]

Anatomical structures relevant to laryngeal mask airway space include the mouth, Oropharynx and Laryngopharynx.

Mouth

The roof of the mouth formed by vaulted palate. Anterior part is formed by hard palate and the posterior part is formed by soft palate. The shape of hard palate is such that a food bolus is directed into the oropharynx inlet with the stiffened soft palate shielding the nasopharynx. There might be some difficulty in passing the laryngeal mask airway into oropharynx, if the angle of approach between the hard palate and posterior oropharyngeal wall is < 90degree. Mouth opening is essential for laryngeal mask airway placement. The normal distance between the upper and the lower incisor teeth in adult patients with normal temporomandibular joint function is 47 mm with a range of 31-55 mm. At least 12mm mouth opening is needed for inserting laryngeal mask airway.

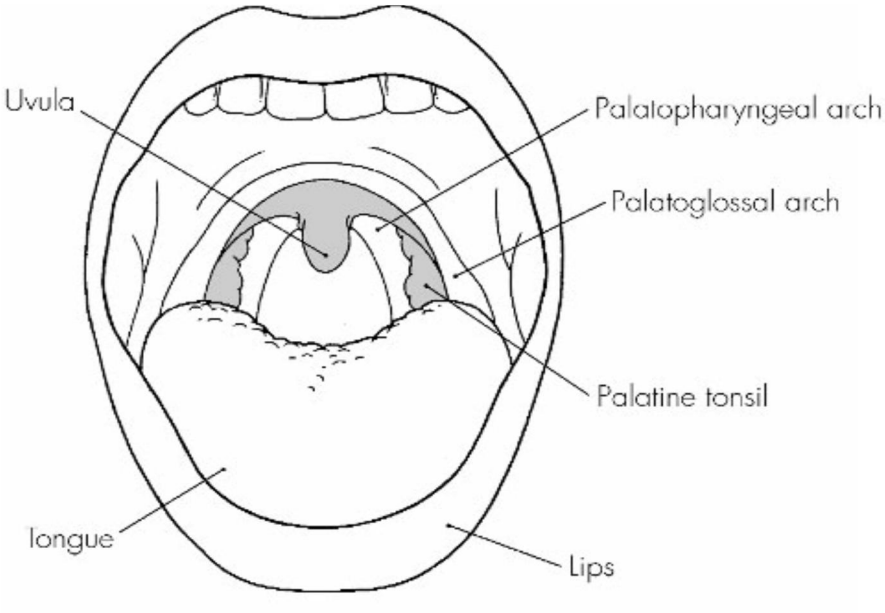

Figure 1: anatomy of oral cavity

TONGUE

Tongue is a muscular organ situated in the floor of the mouth. It has an oral part that lies in the mouth and a pharyngeal part that lies in the pharynx. The oral and pharyngeal parts are separated by a V shaped sulcus, the sulcus terminalis.

ORAL PART

Placed on the floor of the mouth. The margins are free and in contact with gums and teeth.

PHARYNGEAL PART

The posterior part of the tongue is connected to epiglottis by the median glossoepiglottic fold and the right and left glossoepiglottic folds. Vallecula is a pouch like area situated on either side of the median fold. The lateral folds separate the vallecula from piriform fossa.

PHARYNX

The pharynx extends from posterior aspect of the nose at the base of the skull down to the level of lower border of cricoid cartilage where it becomes continuous with Oesophagus, and the respiratory tract through larynx. The soft palate partially divides the pharynx into two, an upper nasopharyngeal portion and a lower Oropharyngeal portion. Pharynx is partially divided by the soft palate into

1) Nasopharynx 2) Oropharynx 3) Laryngopharynx

1) Nasopharynx

This is First part of pharynx situated posterior to the nose, and superior to the lower border of soft palate. The roof and posterior wall form a continuous slope, opposite the posterior part of body of sphenoid, basiocciput and anterior arch of atlas. Under the mucous membrane, opposite the basiocciput is a collection of lymphoid tissue called nasopharyngeal tonsil or adenoids.

2) Oropharynx

It is the middle part of pharynx, starts below the soft palate and extends to hyoid bone to continue as laryngopharynx at the level of upper border of the epiglottis. Behind, it is supported by the body of the axis vertebra. In the lateral walls of oropharynx are situated the tonsillar pillars or fauces. The anterior pillar contains glossopharyngeal muscle and the posterior pillar contains palatoglossus muscle.

3) Laryngopharynx

It is also called hypopharynx. It is located posterior to the larynx. It starts from upper border of the epiglottis and ends in lower border of the cricoid cartilage. The lateral wall presents a depression called piriform fossa, one on each side of the inlet of larynx.

The fossa is bounded medially by aryepiglottic fold and laterally by thyroid cartilage and thyrohyoid membrane. Beneath the mucosa of the fossa, there lies the internal laryngeal nerve. Removal of the foreign bodies from the piriform fossa may damage this nerve.

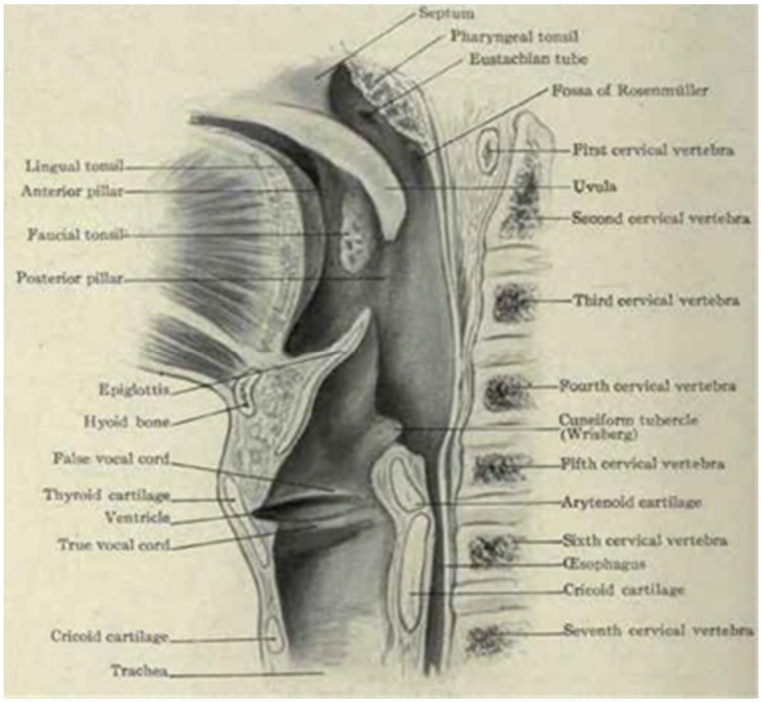

Figure 2: anatomy of pharynx

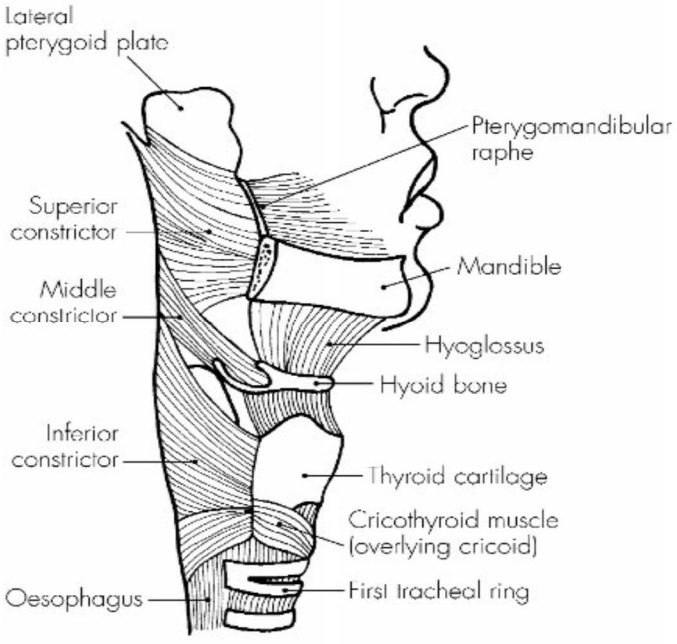

Fig 3: Side view illustrating the 3 constrictors of the pharynx and their attachments.

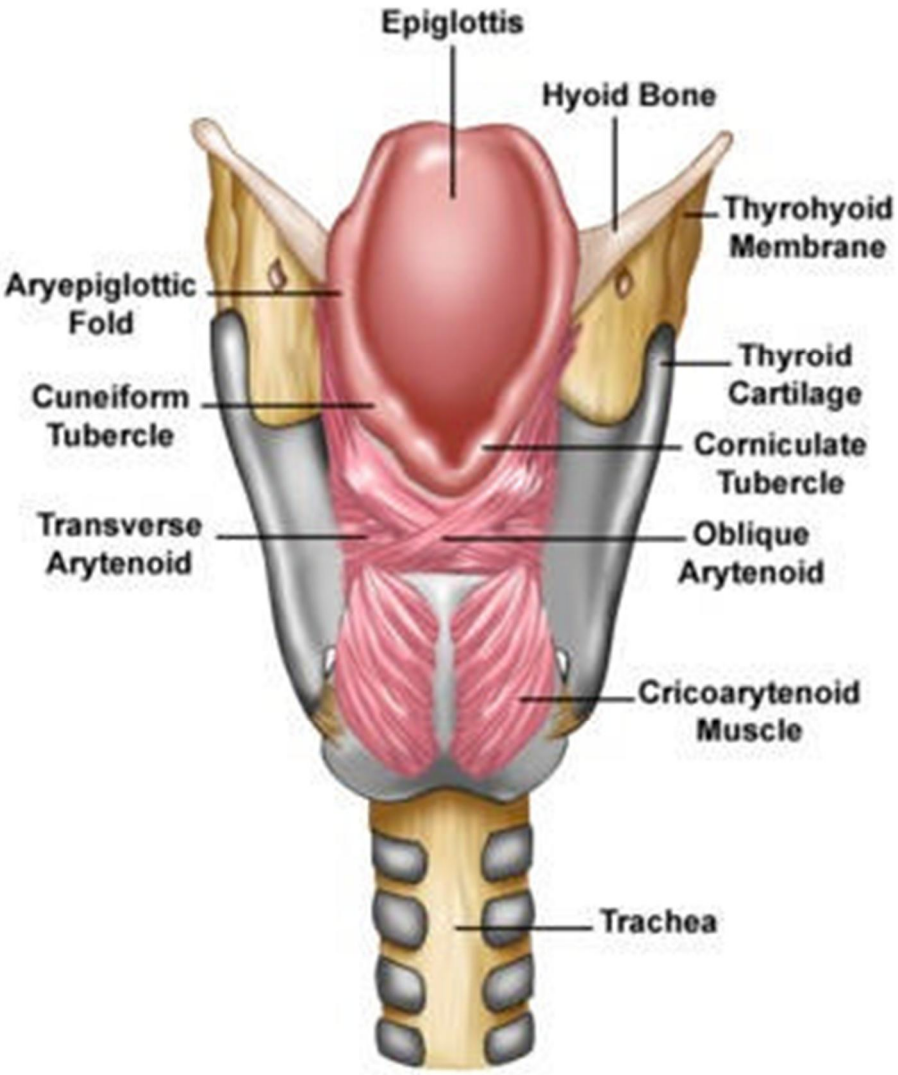

Figure 4: anatomy of larynx

BASIC PHARMACOLOGY

BASIC PHARMACOLOGY[36,37,39]

GLYCOPYRROLATE

Structure:

An anticholinergic which acts by antagonistic action over muscarinic acetylcholine receptors. It acts as a Competitive antagonistic action.

It was synthesized in 1960 .It is a Synthetic quaternary amine. It is formed by combination of mandelic acid plus organic base (tropine/scopine/N-methylated derivation of atropine). Anticholinergic drugs have cationic portion which fits in muscarnic receptor

Mechanism of action:

It is highly selective competitive antagonist at all muscarnic receptors. Muscarnic receptors are G-protein coupled receptors whose second messenger varies accordingly .Anti sialogogue property due to blockage of M_3 receptors present over respiratory tract & salivary gland.

Pharmacokinetics:

It is incompletely absorbed from intestinal tract due to complete ionisation. Onset of action in -IV-(slower compared to atropine): 2 to 3 min.

Duration of action:

Parenteral : Vagal block (2-3 hours), Inhibition of salivation -7 hours

Oral : Anticholinergic effect (8-12 hours)

Volume of distribution :

Adult-1.3-1.8 lit/kg

Children-0.2-0.62 lit/kg

Clearance:

Clearance of glycopyrrolate is rapid than atropine 1.3 m vs 2.3 m (for atropine). 80 % of drug is eliminated unchanged via urine. Elimination is prolonged in uremic patient..

Uses :

1. Anti sialogogue property due to M_3 blocking property . used as premedication . Potent inhibitor of salivary and respiratory secretion.Do not cross BBB/placental barrier. So it does not cause sedation which is predominantly seen in scopolamine.
2. Pharmacologic enhanced antagonist of non-depolarising muscle relaxants with neostigmine requires concomitant administration of glycopyrrolate

3. Because ,this drug acts over M_2 receptors on SA node & causes higher in HR (this higher in HR not seen via IM injection)
4. This compensates the bradycardia caused by neostigmine that may significantly leads to cardiac arrest
5. Decreased acid secretion in stomach & so may be used for peptic ulcer.

Dosage:

5 to 10 mic/kg, Upto 0.2 to 0.3mg in adults**,** Package 0.2 mg /ml, Tab 1.5 mg

Side effects:

Dryness of mouth and skin, Anhydrosis, Flushing , Blurring of vision

Constipation, Urinary retention, Palpitation, Cyclopegia, Hyperthermia (especially in infants), Cardiac arrhythemias.

Special considerations:

- For glaucoma patients
- For parturients (pregnancy-placed under category B

SEVOFLURANE

Sevoflurane was Synthesised more than 40 years ago at Travenol laboratory .But it was introduced only in the late 1980s though its recovery is rapid because of its unstability in presence of sodalime.

Introduction:

It is a fluorinated methyl isopropyl ether.

Partition co-efficient:

Describes relative affinity of an anaesthetic for two phases when an equilibrium has been achieved.

Blood gas coefficient- for sevoflurane 0.65

TABLE : 1

	Blood gas	**Brain-blood**	**Liver blood**	**Kidney blood**	**Muscle blood**	**Fat-blood**
Sevoflurane	0.65	1.7	1.8	1.2	3.1	4.8

1. Non pungency, minimal odour
2. Rapid rise in alveolar anaesthetic concentration & low blood gas partition co-efficient in low blood solubility-makes induction & recovery faster
3. When compared to isoflurane ,recovery is 3 to 4 minutes faster.

Inhalational induction:

4% to 8% sevoflurane in 50% mixture of N_2O & O_2 can be achieved in 1 minute

Biodegradation:

It is metabolised by liver microsomal enzyme p 450

It does not form aryl halide in this regard, it differs from rest of the flurane . so no hepatotoxicity & cross-sensitivity seen in case of sevoflurane.

Effects of sevoflurane over systems:

EEG:

< 0.4 MAC – higher frequency & voltage

At 0.4 MAC – cerebral metabolic O_2 begin to decrease abruptly. -amnesia occur. Transition from wakefulnese to unconsciousnese

1 MAC - Frequency decrease & voltage increase

Sevoflurane - Dose related EEG changes

Non anaesthetic MAC concentration - initial increase in frequency & lowering of voltage.

At anaesthetic MAC - increase voltage

Seizure activity - in presence of deep level of anaesthesia / hypocapnia / auditory stimulation- do not produce evidence of convulsive activity in EEG

It suppresses convulsive activity induced with lidocaine.

Mental function and awareness:

Significant pharyngeal dysfunction occur at 25% MAC awake

To restore pharyngeal reflexes-90% of elimination is required.

Cerebral blood flow:

Usually normocapnia with >0.6 MAC – volatile anaesthetic produce cerebral vasodilatation ,decrease cerebral vascular resistance & dose depedent increase in CBF ,Sevoflurane produces dose depedent cerebral vasodilatory effect and decreases Cerebral metabolic O_2 requirement.

Circulatory effects:

Mean arterial pressure- fall in pressure principally due to decrease in systemic vascular resistance

Heart rate - increase in HR (seen only in > 1.5 MAC)

Cardiac output - decrease (At 1 & 1.5 MAC

- At 2 mac- cardiac out put recovers to nearly to conscious level

Right arterial pressure – no change

Cardiac dysrythmia – minimal to non existing prolongation with sevoflurance.

Accessory pathway conduction – sevoflurane no effect on atrioventricular /accessory pathways-acceptable drug for patients undergoing ablative produces.

Cardiac protection:

Patient receiving sevoflurance for cardiac surgery has less myocardial injury during first 24 hrs postoperative period than patient receiving Propofol cardio protectiveness of sevoflurane is seen when it is administered throughout surgery than as a part of surgery.

Ventilation effects:

Ventilator response to CO_2: Dose dependent depression of ventilation characterised by decrease in ventilator response to CO_2 & increase in $PaCO_2$,Profound decrease in ventilation leading to apnoea but 1.5 & 2 mac leads to increase $PaCO_2$..

Ventilatory response to hypercapnia:

Sevoflurance induced decrease in hypoxic responsiveness are not different in men & women. It is usefull in thorasic surgery as it is a potent bronchodilator

Airway resistance and irritability:

Risk factors for branchospasm

Preoperative respiratory track infection, Endotracheal intubation ,COPD

In patient with COPD, sevoflurane cause bronchodilatation & decrease airway resistance (after intubation in patient without asthma)

- At 1 MAC ,sevoflurane suppress response to tracheal intubation
- No irritant property
- But exposure of sevoflurane to dessicated CO_2 absorbent'especially with KOH result in production of toxic gases leading to airway irritation & impared gas exchange..

PROPOFOL

STRUCTURE OF PROPOFOL:

Propofol consists of phenol ring substituted with two isopropyl groups. It is not water soluble.1% Propofol present as oil-in – water emulsion containing 10% soyabean oil ,2.25% glycerol ,1.2%purified egg phosphatide/egg lecithin.It is not contraindicated to use in egg allergic individuals because egg allergies involves reaction to egg white(egg albumin),here egg lecithin extracted from egg yolk.

COMMERCIAL PREPARATION OF PROPOFOL:

Current formulation contains soyabean oil as oil phase and egg lecithine as emulsifying agent which is composed of long chain triglycerides .This favours bacterial growth and also increase plasma triglyceride level when there is prolonged intravenous infusion .As it favours contaminations ,the opened vial has to be used within 6 hrs to avoid this ,preservative such as 0.005% disodium edetate or 0.025% sodium metabisulfate is added which retards the growth of microbes.

MECHANISM OF ACTION:

GABA is the principal inhibitor neurotransmitter in the CNS. Propofol is relatively selective modulator of $GABA_A$ receptors therby facilitating inhibitory neurotransmission. Interaction of Propofol with specific components of $GABA_A$ receptors decreases the rate of dissociation of inhibitory neurotransimitter there by increasing the duration of GABA activated opening of cl^- channel ,there by increasing the transmembrane conductance of cl^- channel resulting in hyperpolarisation of post synoptic cell membrane and functional inhibition of post synaptic neuron .Propofol action not reversed by BZD antagonist flumazenil.

PHARMACOKINETICS:

Propofol has rapid onset of action due to very short distribution half life (2-8 min) following single bolus .Because of it' s rapid and complete awakening ,causes this Propofol to use in day care surgery .Age is a key factor determining Propofol infusion rates .For elderly patients ,smaller induction dose is recommended because of their small volume of distribution.To provide controlled target infusion of Propofol Diprifusor is used for which patients age ,weight ,and desired target concentration has to be entered..

BIOTRANSFORMATION:

Clearance of Propofol from plasma exceeds hepatic blood flow indicating the extra hepatic metabolism. Hepatic oxidative metabolism by cytochrome p 450 is important in removing this drug. By extensive hepatic metabolism this drug converted to inactive water soluble sulfate and glucuronic acid metabolities that are excreted by kidney .It also undergo hydroxylation to form 4 -hydroxy Propofol which is then conjugated with glucuronides or sulfate. 4 –Hydroxy Propofol has one third of hypnotic activity of Propofol..About less than 0.3% of a dose is excreated unchanged in urine Apart from hepatic metabolism ,extrahepatic metabolism is due to pulmonary uptake and renal clearance.

PULMONARY UPTAKE OF PROPOFOL:

In lungs Propofol transformed to 2,6 diisopropyl1,4 quiniol and then released in to circulation .Pulmonary uptake influences initial uptake of Propofol .Human kidneys plays an important role in the elimination of Propofol.Glucuronidation is the major metabolic pathway for Propofol and UDP glucuronyl transferase are expressed in brain and kidney.

ELIMINATION HALF LIFE OF PROPOFOL is 0.5 to 1.5 hrs .

VOLUME OF DISTRIBUTION is 3.5 to 4.5 liter per kilo gram

CLEARANCE is 30 -60 ml /kg/min

Context sensitive half time for Propofol infusion lasting up to 8 hrs is <40 mins. Though its eliminated by liver and kidney there is no evidence of impaied metabolism by cirrhosis of liver /renal dysfunction patients.

CLINICAL USES:

Become the induction of choice when complete and rapid awakening is desirable .

It become a part of conscious sedation or as a part of balanced or total intravenous anaesthesia.

Dosage of Propofol:

For induction of anaesthesia ;1.5 to 2.5 mg / kg(iv)with blood level 2 to 6 µg/ml. Awakening occurs at concentration of 1 to 1.5 mic /ml

Intravenous sedation ;25 – 100 µg /kg /min.

Maintenance of anaesthesia ;100-300µg/kg /min

Anti emetic effect ;10 mg iv

EFFECT ON ORGAN SYSTEM:

CENTRAL NERVOUS SYSTEM:

Propofol decreases $CMRO_2$,cerebral blood flow, intracranial presser. Large doses of Propofol decreases systemic blood presser there by decreases cerebral perfusion pressure. Cerebral auto regulation in responses to change in systemic blood presser and reactivity of cerebral blood flow to change in Paco2are not affected .Propofol produce cortical EEG changes ,which in high doses is able to produce burst suppression .Awake craniotomy which is performed for the management of refractory epilepsy , Propofol is used as it does not interfere with electro corticographic recordings . But Propofol has to be discontinued 15 min before the recording. Propofol produces the memory impairment as midazolam whereas thiopentone has mild effect , fentanyl no effect over memory..

CARDIOVASCULAR SYSTEM:

Propofol produces decrease in systemic blood pressure .This decrease in blood pressure due to decrease in cardiac output and ,decrease in SVR. The decrease in SVR is due to inhibition of sympathetic vasoconstrictor nerve activity. Decrease in cardiac output is due to negative inotropic effect resulting from decrease in intracellular Ca^{2+} availability secondary to inhibition of trans – sarcolemmal Ca^{2+}influx. Propofol effectively blunts the hypertensive responses occurs due to endotracheal intubation, direct laryngoscopy and LMA .It also blunt

the increase in epinephrine concentration which occur as a result of sudden increase in desflurane at a Propofol concentration of 2 mg /kg iv. The fall in blood pressure due to induction by Propofol is exaggerated in old age ,compromised left ventricular function due to coronary artery disease.The pressure response to ephedrine is augmented by Propofol.

HEART RATE:

Bradycardia and asystole has been observed in patients receiving induction with Propofol. This is due to decrease in sympathetic activity resulting in predominance of parasympathetic action .Propofol does not alter sinoatrial, AV node in normal patients or patient with wolff-parkinson syndrome.so Propofol is recommended during ablative procedures and while using Propofol there is disappearance of delta wave in EEG. Bradycardia following Propofol administration does not respond to atropine. so treatment of choice for Propofol induced bradycardia is isoproterenol.

LUNGS:

Propofol produces dose dependent depression of ventilation with apnoea occuring in 25%to 35%of patients.

Propofol decrease tidal volume ,decreases respiratory rate ,decreases ventilatory responses to CO2, arterial hypoxemia.

At sedative concentration Propofol depress ventilator responses to hypercapnia, due to action central chemoreceptors. Hypoxic pulmonary vasoconstriction seem to remain intact in patient receiving Propofol..

HEPATIC AND RENAL FUNCTION:

Normally ,there is no hepatic or renal injury. But when there is accompanying lactic acidosis ,bradyarrhythemia, rabdomyolysis with prolonged infusion of Propofol produces hepatocellular damage. Infusion of Propofol leads to green colour urine reflects presence of phenol in urine .In gout ,urinary uric acid excretion is increased presenting as cloudy urine and it does not indicate the alteration in renal function.

ADVERSE EVENTS:

ALLERGY:

Di-isopropyl side chain and phenol nucleus are responsible for allergy.

LACTIC ACIDOSIS/ PROPOFOL INFUSION SYNDROME:

Pediatric and adult patients receiving prolonged high dose infusion of Propofol (>75 mic/kg/min) for more than 24 hrs, develop lactic acidosis(increased anion gap).Initially –discontinuation of Propofol and extra corporeal membrane oxygenation has to be done.

SUPRAGLOTTIC AIRWAY DEVICE

SUPRAGLOTTIC AIRWAY DEVICES[35,38]

The LMA was conceived and designed by Dr. Archie Brain in UK in 1981 and following prolonged research was released in 1988. Dr. Archie Brain worked on the idea of decreasing the size of anaesthetic mask so that instead of applying it over the face it could be applied over the laryngeal opening. The first independent clinical trial of LMA was carried out at north wick park hospital in 1987 and within 1 year the design was finalized and four sizes were available by September 1990 all British hospitals performing operations add LMA on their anaesthesia machines. But this device was also not full proof against complications like aspiration.

CLASSIC LMA:

The classic LMA was invented by Dr. Archie brain in the year 1981 and introduced in 1988.

The classic LMA is made from medical grade silicone. It consists of a curved tube connected to an elliptical spoon shape mask at a 30 degree angle. There are 2 flexible vertical bars at the entry of the tube into the mask to prevent obstruction of the tube by the epiglottis. The mask is surrounded by an inflatable cuff. An inflation tube and self-sealing pilot balloons are attached to the proximal wider end of the mask. A black line running longitudinally along the posterior

aspect of the tube helps to orient it after placement. At the machine end of the tube it has a standard 15mm connector.

Fig 5 : Classic LMA

The classic LMA is available in 8 sizes and the choice of the correct size is according to the patient's weight. When there is doubt, a larger than the smaller size should be chosen for the first attempt.

Indications :

1) As an alternative to mask while giving anaesthesia.
2) Can be used in minor surgeries.
3) As a rescue device in failed intubation.

4) As an emergency airway management in CPCR.

5) As a tool for airway management in the pre hospital setting in patients in whom positioning or prolonged extrication does not allow for endotracheal intubation.

6) As a conduit for intubation for especially when direct laryngoscopy is not successful.

CONTRAINDICATIONS: In patients with:

1. Restricted mouth opening.
2. Complete upper airway obstruction.
3. Increased risk of aspiration.
4. Suspected or known abnormalities of supraglottic anatomy.
5. Need for higher airway pressures.

INSERTION:

Standard Technique

LMA is inserted with a fully deflated cuff through midline or diagonal approach with patients in sniffing position .The head is stabilized with the non inserting hand and mouth can be opened by an assistant. The LMA is held like a pen with the index finger over the shaft at its junction with the cup. The aperture of the cup should face anteriorly and the tip is placed over hard plate with shaft

parallel to the floor .If jaw is held open it should be released before insertion .In case of restricted mouth opening, LMA is passed behind the molar teeth into the pharynx .The LMA is held with index finger and pressed over the hard palate . Resistance is felt if the tip of the cup is folded on itself or if it faces any irregularity in its passage. If such a resistance is felt LMA should be withdrawn and reinserted .The course of LMA changes as it slides in to the pharynx ,the index finger is advanced further with arm in pronation .The black line on the LMA shaft is always positioned mid line and any change of this position denotes misplaced. Lateral approach can also be used especially in high arched palate patients .Always ensure that the tip of cuff is flat and well approximated with the palate. If initial insertion not fruitful ,different maneuvers can be tried .they are; (i) insertion from the angel of mouth (ii) pulling out the tongue anteriorly (iii)giving jaw thrust (iv)adjusting the head position (v) rotating the cuff to 180^0 when inside oropharynx.(vi)using CPAP while inserting . (vii) slight lateral rotation, (viii) partial cuff inflation ,(ix) introducing a finger posteriorily to the cup as a glide (x) using laryngoscopy and stylete for insertion .The cup should rest on the floor of hypopharynx with sides facing pyriform fossa and superior border of the cup facing posterior most tongue .The epiglottis lies over the cup and sometimes the oesophagus lies within the rim of the cup.

Using the LMA family :

Always keep LMA of 3 sizes use- one the chosen size and one smaller and one larger sizes. Use only air to inflate the pilot balloon, using a Propofol or other organic substance contaminated syringe cause damage to the LMA.

Pre- use inspection:

Visual inspection:

Look at the tube for any change in colour, foreign body , cuts ,tears .Examine the cup and its aperture for any damage or foreign body .The connector is checked for its tight fitting .

Deflation/inflation

(i) Deflate the cup gently and look for re inflation even after removal of syringe from the inflation valve .If it inflates it suggest damaged valve or leaking cuff.

(ii) Inflate the cuff with double the volume recommended and look whether the cuff holds pressure for more than 2 min any change in the LMA cup size or shape warrants disposal of LMA. Look for the pilot balloon width if excessively inflated, it shows impending rupture .

Mask preparation

Deflate the cuff full with a syringe after pressing it over a hard surface or using a deflating stool given by manufacture. The cuff should be free of wrinkles. Using a deflating tool lengthens the life of the cuff providing superior and consistent shape.

Apply a lubricant at the posterior surface of cuff before insertion with a care not to press over the bowel. Water soluble gel is preferred lubrication with lidocaine gel may decrease retching and cough but may also delay return of reflexes and cause allergic reaction. Silicone containing gels or sprays soften and swell the cuff.

Anaesthetic induction

An adequate general anaesthesia or topical anaesthesia is required before insertion to blunt airway reflexes and a depth for its insertion but not so far tracheal intubation. Good jaw relaxation is considered as a deep plane for insertion.

Cuff inflation and assessing position and function:

For proper inflation of cuff a pressure gauge is used and cuff is inflated to up to 60 cm water. Cuff pressure can also be assessed by feeling the pilot balloon tension. The pilot balloon should be cylindrical and an overinflated cuff will be

spherical. Inflation of the cuff is done gradually over three to five seconds without holding the tube. After inflation of cuff a slight upward movement of the LMA is seen as it seals the larynx from pharynx . Also a swelling in front of neck is seen. Oro pharyngeal leak is also assessed by inflating the cuff with half of the maximum pressure. The volume of the cuff is less important than choosing the cuff size as large size LMA can give a better seal. The leak pressure for IPPV should more than 20 cm H_2O and for spontaneous respiration more 10 cm H_2O

FIXATION:

After fixation of LMA a bite block is always kept between the molars to prevent biting of LMA. An airway cannot be used as both LMA and airway occupy midline. The tube should be secured with a tape , with a care not to twist it.

Intraoperative management:

Any abnormal sound heard around the LMA should alert for light plane of anaesthesia, displacement of LMA, airway closure, closure of glottis, decrease lung compliance or a leak in cuff. Care should be taken while trying to inflate cuff as it further displaces it away from pharynx by increasing tension. At times removal of air from cuff can help. Presence of fluid in tube indicates regurgitation which is also accompanied by coughing or breath holding. At such a situation head

end is lowered and airway suctioned after circuit disconnection. It does not warrant removal of LMA but Endotracheal intubation should be made ready.

Emergence from anaesthesia:

Removal of LMA should be done either in deep plane or in a full awake patient with all intact protective reflexes. LMA can be left insitu until patient full recovers with return of airway reflexes and phonation will give a secured airway. Such a level can be assessed by return of swallowing reflex. If LMA is removed during light plane aspiration of secretion can occur. It can also cause cough, gagging or laryngospasm also removing LMA before they responds to commands inspite of return of swallowing, incidence of gastro oesophageal reflex increases. It can be decreased by removing LMA in deep plane. It also prevents bronchospasm and damage to LMA. It is deserved in intra ocular surgeries but avoided in a difficult airway patient. The disadvantages are laryngospasm, airway obstruction or regurgitation.

Care and cleaning:

After use reusable LMA is cleaned as early as possible with lukewarm water and 8-10% Sodiumbicarbonate solution. Sodabicarb helps to remove all secretions struck to LMA. Detergents contain irritants hence should not be used. The tube is cleaned with a pipe cleaner brush with a care not to damage the cup

bars. The inflation valve is kept away from any solution. Finally LMA is cleaned in a running water dried, kept in pouch. Avoid water entering the cup. If accidentally water enters cup, cup is held up and water is squeezed downwards. LMA is then kept in a warming closet at 60 degree celsius with a syringe without a plunger in the inflation valve. Before autoclaving all air must be removed as any residual air can expand and damage the cup/valve/pilot balloon. LMA can be shaped into any form by bending it when it is placed for autoclaving. An open valve can cause air to escape.

LMA can be autoclaved up to a temperature of 135 degree celsius but temperature more than this can cause damage to LMA. It is further allowed to cool to room temperature autoclaving damages the bond between connector and tube but not the air tight seal. WHO guidelines says that the fore mentioned cleaning and sterilization or sufficient for inactivating common bacteria, fungi, viruses. Only in a known case of spongiform encephalopathy LMA should be destroyed after it is used.

Liquid chemical agents or ethylene oxide should not be used to clean or sterilize the LMA. They are adsorbed onto the silicone and can cause pharyngitis and laryngitis as well as shorten the LMA life.

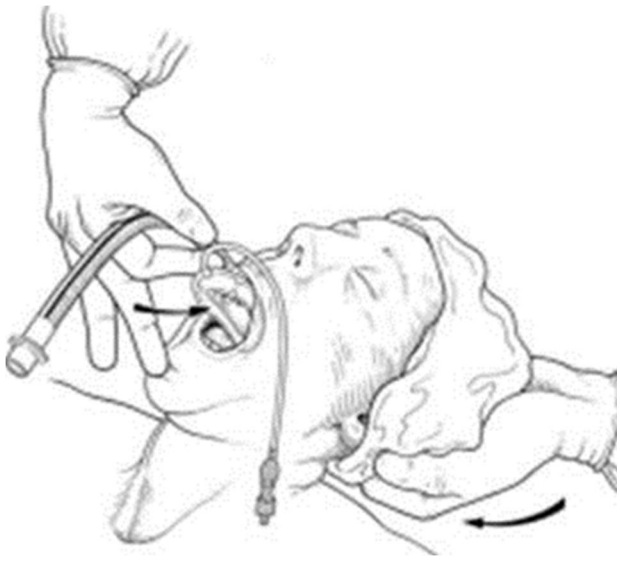

Figure 6 : Step 1 – Initial insertion of the laryngeal mask

Figure 7 : Step 2

Figure 8 : Step 3

Life Span

With careful use and strict adherence to cleaning and sterilization procedures, a laryngeal mask airway will last for a long time. The recommended maximum number of uses by the manufacturer for the LMA-Classic is 40, but up to 200 uses have been reported. With repeated use, there is a decrease in elastance , an increase in cuff permeability, and a loss in strength of the airway tube. It may be possible to exchange a malfunctioning inflation valve on an LMA.

DESCRIPTION OF I-gel [14]

It is a new extra glottis mask airway device with gastric access. The I– gel has evolved as a device that accurately positions itself over the laryngeal frame work providing a reliable perilaryngeal seal . It also does not produce compressive trauma.

The I-gel design

This extraglottic airway device has no inflatable cuff .

Advantages of I-gel are;

(i) Insertion is easy ,insertion time is less ,no need trained person to insert in emergency airway management even paramedical worker can insert the device.

(ii) Tissue compression is less, less chance of ischemic events.

(iii) It has integral bite block.

(iv) Position of the device is stable after insertion whereas in classic –LMA it comes forward after inflating cuff .

Parts of I-gel

1. Soft non-distendable cuff
2. Channel for gastric access.
3. Supraglottic blocker.
4. Oral cavity stabilizer.

5. 15mm connector.

Figure 9 : Parts of I-gel

1. Selection of Proper size:

It is selected based upon the patient weight , sex , anatomical variation. Larger size I-gel might be required in following conditions; (i) if the neck is cylinder shaped (ii) if there is wide laryngeal cartilages. Smaller size I-gel might be required in following conditions (i) if the neck is broad (ii) if there is small laryngeal cartilages . Patients with central obesity might not require large size I–gel. A size that is equal to ideal body weight for their height can be used.

If there is leak , the seal is not adequate, particularly during controlled ventilation, one size larger may be needed.

2. Pre-use checks

- Make sure I –gel is not damaged before opening the package.
- Airway should be patent, there should not be any foreign particles which might obstruct the distal openings .
- Carefully look at the inner surface of bowl it should be smooth, free from any particles ,there should not be any breaks ,both the channels are intact.
- Discard the device if there is any abnormality is detected.

Pre-use preparation

1. Always wear gloves, use a small bolus of lubricant which is water based , onto the smooth outer surface , do not use silicone.
2. Do not touch the cuff of the device with hands.
3. Dentures should be removed prior to attempting insertion.

Recommended insertion technique:

1. After the lubrication of I-gel ,it should be grasp firmly along the integral bite block. The I-gel cuff should be facing towards the chin.
2. Position; ‘sniff position’.(head extended and neck flexed).

3. The soft tip of device should be inserted into the mouth towards the hard palate.
4. Move the device continuously along the hard palate until there is a definitive resistance.
5. In a properly placed I–gel the tip will be positioned in upper oesophageal opening ,the cuff will be positioned against the laryngeal cartilage. There is no need bite block.It has to be taped.
6. There might be 'give-way' when bowl of the I-gel crosses through the faucial pillars . We have to stop the I-gel ,do not repeatedly push I-gel down , whenever there is resistance is felt.
7. Maximum three times can be attempted in one patients .

Emergence from Anesthesia

Patients with IPPV

At the end of the surgical procedure, patient should be reversed . The patient might not be required reversal if there is regular breathing pattern is regained or presence of adequate protective reflexes.

Recovery and removal

Removal of I-gel should be done either in deep plane or in a full awake patient with all intact protective reflexes. I-gel can be left insitu until patient full recovers with return of airway reflexes and phonation will give a secured airway. Such a level can be assessed by return of swallowing reflex. If I-gel is removed during light plane aspiration of secretion can occur. It can also cause cough, gagging or laryngospasm also removing I-gel before they responds to commands inspite of return of swallowing, incidence of gastro oesophageal reflex increases. It can be decreased by removing I-gel in deep plane. It also prevents bronchospasm and damage to I-gel. It is deserved in intra ocular surgeries but avoided in a difficult airway patient. The disadvantages are laryngospasm airway obstruction or regurgitation.

CONTRAINDICATION: to use gastric channel:

1) Varices in the oesophagus.

2) Upper gastro intestinal bleed.

3) Oesophageal trauma.

4) Upper gastro intestinal surgery.

5) Bleeding /clotting abnormalities.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

The development of the LMA began in 1981 at the Royal London Hospital, Whitechapel, in the East End of London. A British anaesthesiologist, Dr Archie Brain, suggested that the Goldman Dental Mask could be modified so as to be positioned around the laryngeal inlet rather than over the nose. Similar devices had been described an half century earlier.[24]

It was Dr. Brain's belief that the two methods by which the anatomical airway was commonly connected to an artificial airway were less than ideal. The most elegant way to join the two involves an end to end junction at the glottis.[24] The face mask falls short because it forms this connection at the mouth and nares, and the tracheal tube goes too far, penetrating the lumen of the respiratory tree. A high lateral pressure is then applied to the delicate epithelial surface, impairing its specialized function and provoking undesirable autonomic responses.[24]

Brain's goal was to develop a device that could rapidly overcome an obstructed airway, and yet, be simple and atraumatic to insert. Initial studies using plaster of Paris casts of the cadaver pharynx indicated the optimal shape of the LMA. A prototype was used on a human patient in 1981, and a successful pilot study on 23 patients soon followed. The LMA was first used in a failed intubation in 1983.[24] Careful observations and clinical experience in more than 7,500 patients

led to small changes in design. The availability of Propofol and the development of a silicon cuff led to greater success in the use of the LMA.[24]

In recent years, I-gel, another Supraglottic airway device with some distinctive features, has been devised that sets it apart from other competitors.

In 1995, Brimacombe J[4] conducted a meta analysis of randomized prospective trials in peer review journals. His aim was to find out the LMA provide any advantage over routine endotracheal tube or anatomical mask . Data were obtained from the selected papers/abstracts about the type of comparative study (LMA vs Tracheal Tube (TT), LMA vs facemask (FM), LMA vs FM vs TT), the study population type and size, the type of surgery, the phase of anaesthesia, studied ventilation mode, LMA user, success with the device and insertion technique. The total study population was 2440 patients and the mean study population size was 47. Advantages of LMA over tracheal tube were included:

(1) It can be placed easily and quickely, takes less time.

(2) It can be placed correctly even by paramedical workers with minimal experience.

(3) Minimal haemodynamic unstability at induction and emergence.

(4) Less rise in intra ocular tension.

(5) Airway tolerance is better than endotracheal tube with minimal anaesthetic doses.

(6) Lesser incidence of airway morbidity during emergence, **Advantages of LMA over the face mask:**

(1) It can be placed correctly even by paramedical workers without any experience.

(2 It gives better oxygen saturation.

(3) Hand fatigue is less.

(4) It gives better surgical field for face , ENT surgeries with good airway maintenance.

Disadvantages of LMA over the Tracheal tube:

1) Oropharyngeal sealing pressor is less.

2) Incidence of gastric insufflation is high.

The author concluded that LMA gives many benefits than endotracheal tube;

(i) It can be used in resuscitation because easy placement ,takes less

(ii) It can be used in patients with cardiovascular disease because good hemodynamic stability during induction and emergence

(iii) It can be used in patients with glaucoma because minimal change in intraocular pressure.

iv) It can be used in open eye surgeries, Otolaryngeal surgeries because less incidence of cough.

In 2008, Richez B et al[26] had done a study on I–gel. It was prospective , an observational method. Sample size is 71 .They included ASA physical status I–II, Proposed surgery was gynaecologic surgery . The authers concluded quality of device was good.They were able to insert in 100% at first attempt . They got score of very easy in more than 90%. It could be used in IPPV ventilation because minimal gastrointestinal insufflation , high leak pressor as well as low peak pressure. They also noticed less pharyngolaryngeal morbidity.

In 2008, Gatward JJ et al[11] did a study to evaluate the no 4 I-gel in 100 adult patients undergoing elective surgery under general anaesthesia. Aim of the study was to find out easiness of insertion , to assess the quality of the device, to find out the positon by clinical method as well as fiberoptic examination, and finally pharyngeolaryngeal morbidity. Physical status ASA 1-3 were included in this study .They were used target controlled infusion of drugs.

The authors concluded that the airway seal given by the I-gel lower than the PLMA, but could be used in IPPV. Insertion of the device into the correct

functional and anatomical position was easy and rapid. I–gel produces less pharyngolaryngeal morbidity. Author also recommended this I-gel securing airway in the difficult airway situations and during CPR.

Table - 2: Showing comparison of i-gel and c-LMA in various studies

Study-author and year	SAD	No. of attempts (I/11/II1)	Time of insertion (seconds)	Airway leak pressure (cmH2O)
Uppal V et al.,[30] 2009	I-gel	38/1	12.2 (9.7-14.3)	25
	c-LMA	39/0	15.2 (13.2-17.3)	22
Janakiram et al.,[15]2009	I-gel	27/23	-	20
	c-LMA	43/7	-	17
Franksen H et al.,[14] 2009	I_gel	36/4	15 (10-60)	29
	c-LMA	34/5	17 (11-180)	20
Parul Jet al.,[15] 2009	I-gel	24/1	3.48±1.41	-
	c-LMA	23/2	7.68±0.69	-
Amini S et al.,[2] 2010	I-gel	48/11	20 (10.4-29.6)	22.6
	c-LMA	46/10	24.2 (11.6-36.8)	19.3
Helmy AM et al.,[13] 2010	I-gel	36/4/0	15.6 (10.72-20.52)	25.62
	c-LMA	32/6/2	26.2 (8.5-43.9)	21.2
Ali A et al.,[1]2010	I-gel	45/5	10.76±5.17	-
	c-LMA	47/3	10.90±5.53	-
Siddiqui AS et al., [28] 2010	I-gel	45/5	-	-
	c-LMA	43/7	-	-
Present study	I-gel	37/3	22.82±4.30	23.82
	c-LMA	36/4	25.8±4.32	19.12

In 2009, Uppal V et al[30] had done a randomized ,crossover, comparative study between LMA unique and I–gel in anaesthetized, paralysed patients. They included 40 patients posted for non emergency surgeries where they required paralyzing agents.

There was no significant difference between the airway leak pressures of the two devices [median (IQR) leak pressures 25 (22–30) vs 22 (20–28) cm H2O for the I-gel and LMA-U, respectively; (P=0.083). The median difference in the insertion time between the two devices was 2.3 seconds in favour of the I-gel. There were three cases of difficult insertion in the I-gel group and one difficult insertion in the LMA-U group .In this study there is no gastric insufflation , and no adverse events were noted.

The authors concluded that that airway leak pressures and number of attempts at insertion were similar between the LMA-U and the I-gel when used by an anaesthetist experienced in the use of both SADs. There was no evidence of gastric insufflation, gastric aspiration during the study. They were found no significant difference in efficacy of seal and first-time successful insertion rate between the I-gel and the LMA-U. The insertion time for the LMA –U was marginally longer than I-gel. They concluded that the I-gel provides a reasonable alternative to the LMA-U for controlled ventilation during anaesthesia.

Limitation of the study:

Since the study is crossover design, they were unable to determine which SAD has higher airway morbidity. Hence this needs a larger non-crossover or an observational study.

In 2009, Janakiraman C et al[15] had done a randomised crossover study comparing the I-gel supraglottic airway and classic laryngeal mask airway in anaesthetised spontaneously breathing patients .Sample size is 50 healthy adults. Primary outcome was successful insertion at first attempt. Secondary outcomes included (1) overall insertion success rate, (2) Ease of insertion, (3) Leak pressure (4) Fibreoptic position. The size of device used was decided by the anaesthetist based on the patient's body weight and the manufacturer's recommendation.

Both airways were inserted in each patient in a random order. Anaesthesia was induced with a Propofol (iv) target controlled infusion (TCI); 7µg/ml for induction and 3.5–5.5 µg/ml for maintenance. Once an adequate depth of anaesthesia was achieved, with above drug the first device was inserted according to the manufacturer's instructions. There are a good seal and adequate ventilation are assessed by absence of any audible leak and presence of a square wave pattern on capnography . At a fresh gas flow of 5 l/ min, the adjustable pressor limiting valve was occluded and the minimum airway pressure at which gas leaked around the airway device was determined (airway leak pressure) by listening for an audible leak. The position of the first device was assessed fibreoptically, following successful insertion, using the Brimacombe score. The initial airway was removed after 5 min of use and replaced with the second airway, after checking the depth of anaesthesia. Similar procedures and measurements were performed. If the insertion

failed after two attempts, the insertion was considered as a failure and the second device was then inserted. If there was an unacceptable leak even at low pressures following successful insertion a larger sized device was used. The same anaesthetist with a personal experience of > 400 c-LMAs and 20 i-gel supra-glottic airway insertions before commencing the study, inserted all devices. The ease of insertion was graded as(1) 0 = easy,(2) 1 = moderate (3) 2 = difficult. Records of any pharyngo laryngeal morbidity including airway obstruction and number of insertions were noted. Hemodynamic parameters like Systolic blood pressure, heart rate and oxygen saturations were noted at baseline, 1 and 2 min following induction. The i-gel was successfully inserted at the first attempt in 54% patients and the c- LMA was successfully inserted at the first attempt 86% of patients. The i-gel that was used first required to be replaced with a larger sized device in 14 patients. In 13 patients size 4 was replaced by size 5.one patient (weight 56 kg) the size 3 was replaced with size 4. The overall success rate after two attempts and resizing of LMA was 84% for I-gel and 92% for c-LMA. Insertion was scored as easy in 40 cases (80%) with I-gel and 45 cases (90%) with c-LMA. The median leak pressure was greater with the I-gel device (20 cm H_2O) compared to the c-LMA (17 cm H_2O) which was clinically and statistically significant.

The study concluded that there is a considerable difference (-32%) in the first time insertion success rate between I-gel and c-LMA. The 95% CI for the

difference, -14 to -47% indicates that the success rate on first attempt with the I-gel is very likely to be >12% less than with c-LMA. However, the overall success rate after resizing of the I-gel improved with a difference of only 8%, although the 95% CI for the difference, -20 to 3%, indicates that the overall success could still be 20% less than c-LMA which is clinically significant. Airway seal was better with the I-gel than the c-LMA which was statistically significant. The number of patients in whom the vocal cords were visible fibreoptically was significantly different between the groups, with the I-gel scoring better than the c-LMA.

The authors concluded that I-gel with current sizing guidelines is not an acceptable alternative to the c-LMA and recommended the manufacturers to review the sizing guidelines to improve the success rate . However, the I-gel has a potential advantage over c-LMA in that it has an integral tube through which stomach contents can be aspirated and also prevent excessive inadvertent ventilation of the stomach.

In 2009, Francksen H et al[27] did a study to compare I-gel with the LMA-Unique in anaesthetised adult patients without neuromuscular blocking agents. Sample size is eighty patients with physical status ASA grade is 1–3 were taken up for study and randomly subjected to the i-gel (n = 40) or LMA-U (n = 40) group, respectively. They induced with 2 mg.kg−1 Propofol and 1 µg.kg −1

Remifentanil . Anaesthesia was subsequently maintained with Propofol (4–8 mg.kg-1 .h-1) and remifentanil (0.2–0.5 µg.kg-1 .h-1). All devices were inserted by a single anaesthesiologist with experience using each of the study devices.

Successful insertion was assured with capnography , bilateral chest movements and auscultation . After device placement, patients were ventilated with a tidal volume (VT) of 7 ml.kg-1 , and respiratory rate of 10 breaths min-1 .Following adverse events during anaesthesia were recorded and defined as '' aspiration/regurgitation, hypoxia (SpO_2 < 90%), bronchospasm, airway obstruction and dental trauma'.

Attaining adequate depth of anaesthesia was assessed with loss of eye lash reflex. Insertion time was measured from 'touching' the device until the first expiratory VT > 200 ml. Following successful placement of the I-gel, a 12 F gastric cathter was advanced in the oesophagus through the gastric channel . A Ph ≤ 2.5 was judged as indicative of gastric fluid. Airway leak pressure was determined by closing the expiratory valve of the breathing circle to 40 cm H2O (fixed fresh gas flow 3 l.min-1) and airway pressure when equilibrium was reached. Leak pressure was measured by keeping stethoscope over epigastrium . Antomical position was confirmed by fibreoptic endoscope through the airway tube to a position 1 cm proximal to the end of the tube. After completion of the study protocol, the anaesthesiologist gave a subjective grading of the handling of

either device, which was graded (1) Excellent,(2) Good, (3) Fair or poor, 18–24 hours after surgery . After surgery complication were assessed .These were (1) Sore throat, (2) Hoarseness and (3) Dysphagia. Symptoms were graded as (1) Nil, (2) Moderate (3) Severe.

In the I-gel group, a successful primary airway was established in 36 patients (90%) on the first attempt and in four patients (10%) on the second attempt. In the LMA-U group, device insertion was successful in 34 patients (85%) on the first attempt and in five patients (13%) on the second attempt. Time required for the first adequate ventilation was comparable between groups (i-gel: median 15 s; range 10–60 s; LMA-U: 17 s; 11–180 s) ($p = 0.45$). Subjective assessment of handling was comparable with the i-gel and the LMA-U. In no patients did arterial saturation decline to less than 90% . The airway leak pressure was significantly high in i-gel group (mean 29 (5) cm H_2O) compared with the LMA-U group [18 (5) cm H_2O (cuff 20 ml); 20 (5) cm H_2O (cuff 30 ml) and 22 (5) cm H_2O (cuff 40 ml)] ($p < 0.0001$) Fibreoptic control of the position of the devices was significantly better in the I-gel group. No gastric inflation occurred with the I-gel device, whereas gastric inflation was observed in the LMA-U group in three patients (7.5%). Gastric catheter placement was successful in all patients in the I-gel group. Insertion of a gastric tube was very easy (first attempt) in 36 cases (90%) and easy in four cases (second attempt) (10%). In all patients, fluid aspirated showed a

pH≤2.5 and therefore the gastric tube was assumed to be in the correct place. Blood staining after removal of the devices occurred rarely (5%) and was comparable between groups. There were no differences regarding postoperative airway complication. No major adverse events occurred during the intra and immediate postoperative period in any patient in both groups.

They concluded that the insertion success, time required for adequate ventilation and subjective rating of the handling of the I-gel and the LMA-U were comparable. However, airway leak pressure was significantly higher in the I-gel group and the fibreoptic score was also significantly better in the I-gel group. The better seal with the I-gel device suggests an alternative to the LMA-U for positive pressure ventilation, especially in patients where higher airway pressures are necessary to achieve a sufficient tidal volume.

In 2009,Kannaujia A et al.[17], did a preliminary study on I-gel . They have taken 508 patients with physical status 1-3 for their study . Objectives was to find out device stability in different neck and head positions ,leak pressure ,how long time taken for achieving successful airway, ease of insertion They used to allow the patients spontaneous breathing without any neuromuscular blocker . Towards the end of the procedure just before discontinuing anaesthetic , they evaluated stability of the device in different head and neck positions. Placing the head and neck in four sequential positions-1) Head on standard pillow, 2) Head rotated to

side, 3) chin lift 4) Head without standard pillow .They were recorded five consecutive tidal volumes under a constant level of anaesthetic depth.

The authors concluded that I-gel has high success rate at first insertion, easy insertion and shorter time to achieve effective airway. They found additional advantages like high seal pressure and stability of the device despite changes in position of head and neck.

In 2009, Jindal P et al[16] had done a comparative study to compare the hemodynamic effects of three supraglottic devices(i) I-gel,(ii) SLIPA (Streamlined Pharynx Airway Liner), (iii) LMA. The sample size was 75 patients of either sex. Inclusion criteria s are (i) Age 20-70 years, (ii) ASA I and II, (iii)scheduled to undergo elective surgical procedures under general anesthesia. All the monitors were placed and baseline reading of HR, BP, SpO_2, ECG were recordeed. After, preoxygenation with 100% oxygen, patients was induced with Propofol 1.5-2.5 mg/kg slowly and Neovec(vecuronium) 0.1 mg/kg facilitate intubation. Above mentioned devices were introduced following the standard techniques by a single anaesthesiologist who is noted to have considerable experience in all three techniques. They have maintained anesthesia with 66% N2O ,33% oxygen, neovec (vecuronium) 0.015 mg/kg and morphine 0.1 mg/kg. Surgeons were requested to wait for 5 minutes after placement of supraglottic devices because surgical stimulai might interfere with the findings. The following data were

collected by a blinded observer: number of intubation attempts, intubation time (time from insertion of the intubating device into the mouth, to time of confirmation by mechanical ventilation), mucosal trauma (blood detected on the intubation device after use), lip or dental injury, episodes of hypoxia during intubation (SpO2 <95%), various hemodynamic parameters like serial heart rate, NIBP , SpO2 and ECG recording were done following time intervals; at the time of insertion, 1, 3 , and 5 minutes following insertion thereafter at the time of removal and then 1 min after removal. At the end of surgery, they used neostigmine 50 µg/kg for reversing neuromuscular block and they assisted ventilation until the patient to breathe spontaneously considering the extubation criteria. When the patients reflexes were regained and was able to open mouth on command, the devices were removed. They found the number of intubation attempts was similar among groups, but intubation time was significantly longer in the LMA group. (3.48 ± 1.41 sec with i-gel, 5.16 ±0.68 sec with SLIPA 7.68±0.69 sec with c-LMA).

LMA group. (3.48 ± 1.41 sec with i-gel, 5.16 ±0.68 sec with SLIPA 7.68±0.69 sec with c-LMA).

Table 5: Comparison of various hemodynamic parameters among all groups i-gel (Group I) SLIPA (Group II) LMA (Group III)

	i-gel SLIPA		LMA
HR	2.4% ↓ at I-0 9.5% ↓ at I-5	2.4% ↓ at I-0	11.2% ↑ at I-0 10% ↓ at I-5
SBP	12.2% ↓ at I-0	8.27% ↓ at I-0	12.5% ↑ at I-0
DBP	16.7% ↓ at I-5	7.31% ↓ at I-5	20% ↑ at I-5
MAP	10.5% ↓ at I-0 18.5% ↓ at I-3	3.44% ↓ at I-0	19.3% ↑ at I-0
RPP	13.7% ↓ at I-0 25% ↓ at I-5	12.3% ↓ at I-5	3.4% ↓ at I-5

I-0: Insertion, I-1: 1 min after insertion, 1-3: 3 min after insertion, 1-5: 5 min after insertion, SLIPA-streamlined pharynx airway liner,HR-heart rate, SBP-systolic blood pressure, DBP-diastolic blood pressure, MAP- mean arterial pressure, RPP-rate pressure product.

I-gel (Group I), SLIPA (Group II), LMA (Group III)

In this study they were observed that i-gel produced less hemodynamic changes than SLIPA which is also a non inflatable supraglottic device and the LMA. This difference could be because SLIPA, is made of moulded plastic (polypropylene) that does not conform to anatomic structures. During the insertion of LMA, pressure response (i.e. increase in heart rate and arterial pressure), may be induced by the passage of the LMA through the oral and pharyngeal spaces, pressure produced in the larynx and the pharynx by the inflated cuff and the dome

of the LMA. During removal of LMA the hemodynamic response is probably triggered by pharyngeal stimulation during reverse rotation of the cuff.

The authors concluded that i-gel effectively conforms to the perilaryngeal anatomy despite the lack of an inflatable cuff, it consistently achieves proper positioning for supraglottic ventilation and causes less hemodynamic changes as compared to other supraglottic airway devices.

In 2010, Amini S [2] et al compared I –gel and the performance of the intersurgical solus – laryngeal mask airway and found the solus LMA has got greater leak pressure , better oropharyngeal seal and good fiberoptic view then the I -gel.

In 2010, Ansar Ali [1] conducted a study to compare the ease of insertion of I-gel and Laryngeal mask airway (LMA).(i) In group A was "LMA" ,(ii) group B was "I-gel" . In this study the patients were pre-medicated with Midazolam 2.5 mg (I/V) 15 min before shifting to operation theatre. Pre- oxygenation was given for three minutes with 100% oxygen. They were induced with Propofol 1% 2 mg/kg I/V . I- gel and LMA were lubricated with distilled water. After 1 minute of ventilation with Oxygen and Sevoflurane using a face mask, LMA or an I-gel was placed in perlaryngeal area . Maintanence of anaesthesia was carried with O_2 , sevoflurane and with intermittent positive pressure ventilation (IPPV). Group A and group B were assessed for ease of insertion of LMA and I-gel. Ease of

insertion LMA or I-gel was assessed according to the following criteria(i). Easy (no airway manipulation), (ii). Satisfactory (required less than two maneuvers), (iii).Difficult (required more than two maneuvers).

In LMA group (Group A) easy insertion was noted in 84% and satisfactory insertion was noted in 16%. While in I-gel group (Group B) exactly same percentage was observed i.e. 84% easy and 16% satisfactory. There was no statistically important association found in ease of insertion between I-gel and LMA (p=1).Mean insertion time was 10.90 ± 5.17 secs in LMA group while that with I-gel group was 10.76 ± 5.53 secs. There is no statistically important difference of insertion time between two procedures (p=0.92). They have found manipulation of the of airway was needed in 30% of the cases with LMA and 48% of the cases with I-gel .There were no statistical association between both groups of airway manipulation requirements (p=0.065). First attempt insertion in LMA group was 94% while second attempt was required in 6% of the cases. In I-gel group, first attempt insertion was achieved in 90% and 10% of the cases required second attempt. There was also statistical non-significant association between the insertion attempt of two devices (p=0.461). Bleeding was only noted in one case of I-gel group. Laryngospasm was noted in 2 cases; one in each. They were not able to secure airway with LMA occurred in 3 and with i-gel in two patients.

They came to conclusion that their study had failed to show the superiority of either device in (i) ease of insertion,(ii) insertion time (iii) number of attempts at insertion.

In 2010, Helmy[13] M et al compared I- gel and classic laryngeal mask airway in an anaesthetized patients breathing spontaneously undergoing various minor elective surgeries and found good hemodynamics and less morbidity in both groups. They have found I –gel insertion needed less skills and takes minimal time to insert, higher leak pressure and less incidence of gastric insuflation.

In 2010, Siddiqui AS[28], et al compared I –gel and laryngeal mask airway – classic in anaesthetized patients with IPPV. They have found both the devices were able to insert easily without any difficulty .They have observed minimal adverse events with good hemodynamic stability during insertion. They came to conculusion that insertion of I-gel was easy and needed little skills as compared to classic laryngeal mask airway at the same time results were not important statistically. They were noticed blood staining on classic- LMA in 18% patients and none of them in I–gel group .Blood staining was due to cuff pressure produced venous engargement, local trauma. They found both the devices were given adequate protection from gastric aspiration and good laryngeals seal.

METHODOLOGY

METHODOLOGY

STUDY DESIGN:

This study was conducted in Institute of Obstetrics and Gynaecology, Chennai from August 2014 to September 2014.The study was a single blinded ,randomized, prospective comparative evaluation of the two Supraglottic airway devices.

Study setting and population:

After obtaining institutional ethical committee clearance, eighty female patients satisfying the inclusion criteria, undergoing short duration gynaecological surgeries under general anaesthesia were enrolled for the study .The insertion of the devices and collection of the data was done by author.

PATIENT SELECTION:

INCLUSION CRITERIA:

- Age : 18 years to 60 years
- ASA : Physical status I, II
- BMI : 20 to 25 kilogram/meter ^{2}
- Airway : MMS I & MMS II
- SURGERY : Minor gynaecological surgeries(elective)
- Who have given valid informed consent.

EXCLUSION CRITERIA:

- Not satisfying inclusion criteria
- Patient with difficult airway
- History of gastro oesophageal reflex disorder
- Patient with acute or chronic respiratory disease
- Patients with musculoskeletal abnormality affecting cervical vertebrae
- Patient with history of allergic reactions to the drugs used in the study, materials
- History of OSA
- All emergency surgeries
- ASA physical status III & IV

The current study was designed to find out whether a functional difference exists between classic–LMA and I–gel in terms of ease of insertion, airway leak pressure and the complications. The sample size was calculated using G power analysis to get an expected 30% difference between the two groups in ease of insertion, Oropharyngeal leak pressure, and the complications.

The study patients were randomly subjected into two groups .Each group contains 40 patients. This is done by using sealed envelope which containing the

name of the group and the patient was asked to pick up the envelope. The envelope was opened by senior anaesthesiologist who did not involved in this study.

Group I - Laryngeal mask airway-Classic (n=40)

Group II - I-gel Group (n=40)

Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination was conducted assessing :

- General condition of the patient
- Airway assessment by mallampatti grading
- Nutrition status and body weight of the patients, height of the patients,
- Detailed examination of the cardio vascular system, respiratory system.

The following investigation were done in all the patients:

- Haemoglobin estimation
- Urine examination for Albumin, Sugar and microscopy
- Standard 12 lead ECG
- X-ray chest
- Blood sugar, Blood urea, Serum creatinine, serum electrolytes

All the patients included in the study were pre medicated with tablet alprazolam 0.5mg and tablet ranitidine 150mg orally at bed time, the previous night before surgery. They were kept nil orally for solids from 10 pm onwards on previous night and for clear fluids up to 2 hours prior to induction.

In preparation room an 18-gauge intra venous cannula was inserted and in operating room normal saline (500ml) was started. Injection Ranitidine 50mg (iv), Injection metoclopramide 10mg (iv), Injection Glycopyrrolate 0.2mg (im) was give 30mins prior to surgery. In the operation theatre ECG, Pulse oximeter, Non invasive blood pressure monitors were connected and base line parameters were recorded and monitored throughout surgery. Optimal sniffing position is achieved by placing a 8to10 cm pillow. $ETCO_2$ monitor was connected after insertion of airway. The classic LMA device was used in Group-I patients. The I-gel was used in Group-II patients.

The patients were pre-medicated with injection midazolam 2mg(iv) ,injection Fentanyl 1mcg/Kg (iv). Then patients were pre-oxygenated with 100% oxygen for three minutes via face mask with closed circuit. Pre induction baseline cardio-respiratory parameters like Heart Rate(H.R), Blood Pressure (B.P) and oxygen saturation (SpO_2) were recorded . Anaesthesia was induced with Inj Propofol 2mg/kg . End point of induction was confirmed by loss of verbal communication. Modified Muzi and colleagues scoring system is used to assess

the tolerance of LMA insertion . According to this following parameters were taken in to account.

(I) Jaw mobility

(a) Completely relaxed jaw score is – 1.

(b) There is mild resistance score is - 2.

(c) Able to open jaw with difficulty score is- 3.

(d) Closed jaw score is - 4.

(II) Coughing or movement

(a) Score 1- none, there is no cough or movements.

(b) Score 2-one or two coughs.

(c) Score 3- three or more coughs.

(d) Score 4- bucking/movement.

(III) Others :

Spontaneous breathing , and Lacrimation.

Ideal score for LMA insertion was less than 2. We have to add 0.5 mg/kg of Propofol and wait for 3 min, if there was any movement happened before insertion or after insertion of LMA.

The lubricated LMA classic was introduced by the classic method and the recommended volume of air was introduced into the cuff. In patients weighing

between 30-50 kilo gram, size 3 classic–LMA was used and in patients weighing between 50- 70 kg, size 4 classic -LMA was used. In patient weighing between 30-60 kg, size 3 I-gel was used. In patient weighing between 50-90 kg, size 4 I-gel was used.

The device was connected to closed circuit. The following parameters indicates ideal placement of airway. Presence of good bilateral symmetrical chest movements, square wave form on Capnograph, normal end tidal CO_2 and stable SPO_2 (more than 95%). The device was secured with adhesive tape. Bite block was kept in case of c-LMA and secured along with it with adhesive tape and the cuff pressure was measured, with help of Portex Cuff Pressure monitor and ensured to be 60 cm of H_2O. Anaesthesia was maintained with using 66% N_2O , 33% O_2 with one to two percent Sevoflurane and without any neuromuscular blocking agents . Immediately after insertion patients were ventilated with IPPV until resuming spontaneous breathing and then patients were allowed to breathe spontaneously till the end of surgery. The surgery was then allowed to commence and intra operative complications like Bronchospasm, Aspiration were noted and treated.

At the end of surgery nitrous oxide and Sevoflurane were discontinued and only O_2 was given until smooth recovery of consciousness. Then the device was removed after regaining consciousness and responding to oral commands . The

oral cavity was examined for any injuries like lip , dental ,tongue and also device was inspected for blood staining, which indicates pharyngolaryngeal injury. Patients were interviewed for any post-operative morbidity like irritation in throat, difficulty in swallowing and any change in voice after 18-24 hours.

In case of failure to insert the supraglottic airway devices properly as judged by an audible leak or inability to achieve adequate chest expansion , the device was removed and reinserted . Maximum three attempts were allowed and if effective ventilation could not be achieved, the patient was excluded from the study and proposed surgical procedure will be carried out using other methods.

PARAMETERS STUDIED DURING THE PROCEDURE

1. Easiness of insertion:

Subjectively graded from 1-3

TABLE - 4
Grading of the Ease of Insertion

1	**Very Easy**
2	**Easy**
3	**Difficult**

Grade : 1 When there is no assistant help for Insertion of device.

Grade : 2 When there assistant help is needed like jaw thurst.

Grade : 3 When first attempt with assistant help failed and second attempt is needed .

2. Time taken for inserting the device:

It starts from picking up the airways , to the time of confirmation of effective ventilation .Time was measured with help of stop clock and it was done by another anaesthetist.

3. Number of Insertion Attempts:

Number of attempts required for correctly placing the each LMA was noted.

4. Airway leak pressure:

Oropharyngeal leak was determined by closing the adjustable pressure limiting valve(APL) of the circle system at fixed gas flow of 3 lit/min (only oxygen) and recording the airway pressure at which equilibrium was reached(maximum allowed was 40cm H_2O).Equlibrium was taken as the point at which an audible sound was detected with help of stethoscope placed just lateral to the laryngeal cartilage. Dragger machine with the provision of recording airway pressure was used. It was measured by two persons. One person will be auscultating the audible sound another portion will record the reading from the monitor.

5. Gastric insufflation:[6]

It was detected by epigastric auscultation with the help of stethoscope, during intermittent positive pressure ventilation.

6. Haemodynamic Parameters:

The following haemodynamics parameters were recorded in all patients,

- Heart rate in beats/min
- Systolic Blood pressure [SBP] in mm of Hg
- Diastolic Blood pressure [DBP] in mm of Hg

The above haemodynamic parameters were monitored in the following time interval---

1. Basal preinduction
2. One minute after insertion
3. Five minute after insertion

7. Injuries:

The patient was examined for any injury of oral cavity like dental and lip injury. Device was examined for blood staining which indicate pharyngolaryngeal injury.

8. Post-operative complication:

The patient was interviewed for any post-operative morbidity like irritation in throat, difficulty in swallowing, change of voice after 18-24 hours.

Figure 10 : Portex cuff pressure manometer

Figure 11: anaesthesia with I-gel

OBSERVATION AND RESULTS

OBSERVATION AND RESULTS

This study has been conducted in eighty ASA physical status I-II adult female patients who underwent elective short duration gynecological surgical procedures . It was ensured that they had fulfilled the inclusion criteria. All eighty patients were included in the study.

The data was analyzed using the SPSS software version 17.0.The Qualitative parameters such as ease of insertion, number of attempts , and the complications were analyzed using the Pearson Chi-square test. The quantitative parameters such as demographic data, the time taken for insertion, the oropharyngeal sealing pressure and the hemodynamics were analyzed using the Student “t test”. The p Value less than 0.05 was taken as significant.

DEMOGRAPHIC CHARACTERISTICS:

TABLE - 5

AGE DISTRIBUTION

Age Group(yrs)	GROUP-I		GROUP-II	
	No. of Patients	Percentage(%)	No. of Patients	Percentage(%)
18 – 30	10	25.00	8	20.00
31 – 40	12	30.00	12	30.00
41- 50	14	35.00	19	47.50
51 – 60	04	10.00	1	02.50
TOTAL	40	100	40	100

TABLE - 6

MEAN AGE (in Years)

	Group I	Group II	P Value	Statistical significance
Mean age (yrs)	**38.60±9.78**	**39.35±9.00**	**0.72**	**NS**

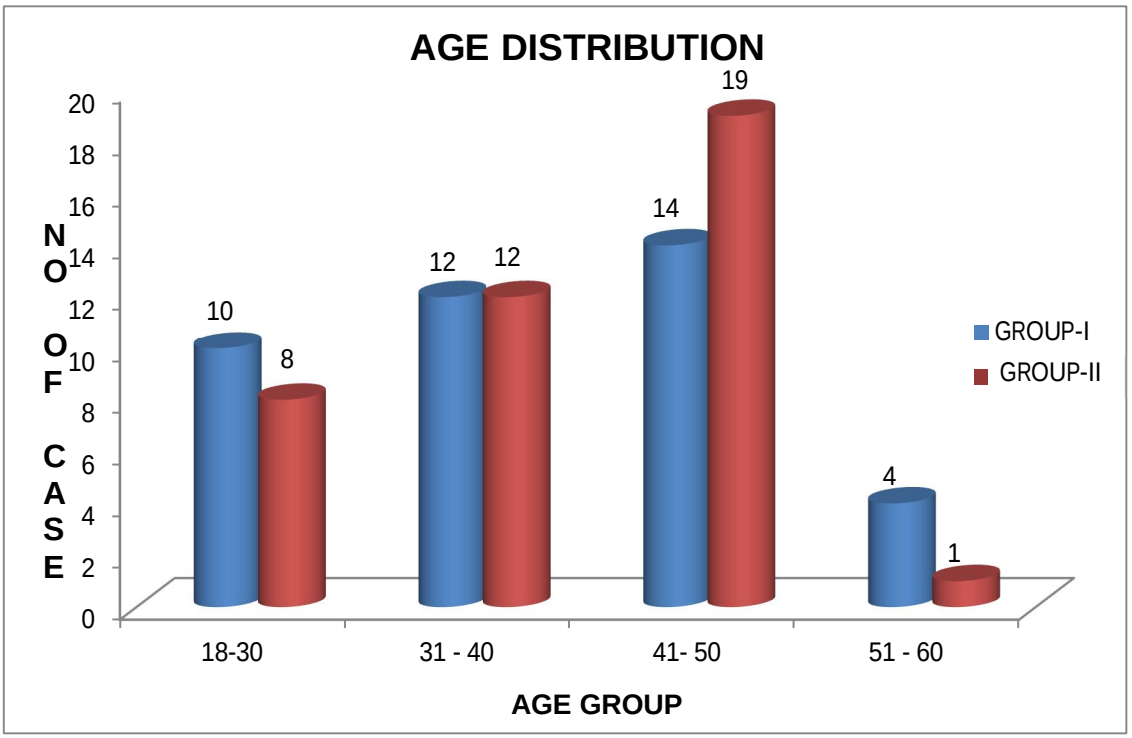

FIGURE 12

Table 5 shows age distribution of patients in both the groups .The minimum age in both group were 21 years. The maximum age in both group were 57 years. The mean age in group 1and 2 were 38.60±9.78 and 39.35±9.00 years respectively There were no important difference between the two groups in terms of age in years .(p= 0.72)

TABLE - 7

Mean BMI

	Group I	Group II	P Value	Statistical significance
Mean BMI	**22.96±0.94**	**22.28±1**	**0.14**	**NS**

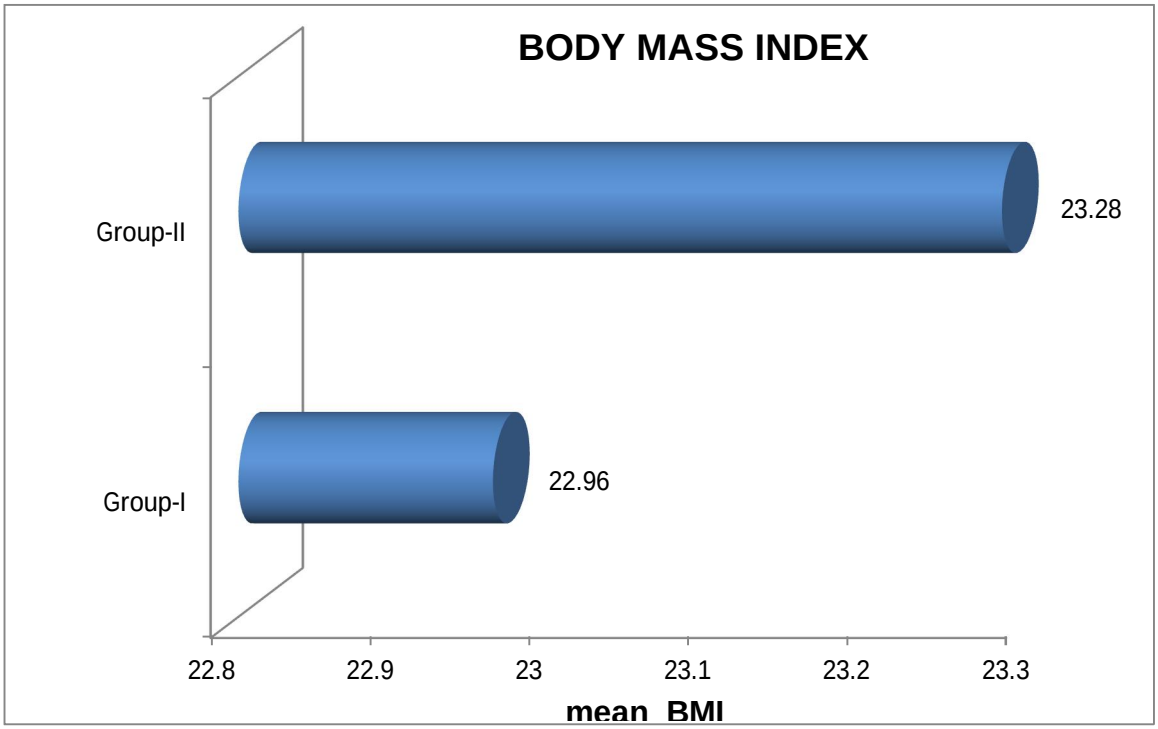

FIGURE 13

Table 7 shows body mass index distribution of the patients. The mean body mass index in group 1 and group 2 were 22.96±0.94 and 23.28±1.00 respectively. There were no important difference in the body mass index of patients between two groups.

TABLE – 8

SIZE OF LMA

Size	GROUP I		GROUP II	
	No of patients	Percentage(%)	No of patients	Percentage(%)
3	15	37.50	15	37.50
4	25	62.50	25	62.50
Total	40	100	40	100

Out of the total number of 80 patients ,size 3 LMA was used in 30 patients and size 4 was used in 50 patients. Out of 30, size 3 LMA 15 were used in group I and 15 were used group II .Out of 50 ,size 4 LMA 25 were used in group I and 25 were used in group II patients.

TABLE – 9

EASE OF INSERTION

EASE SCORE	GROUP-I		GROUP-II	
	No of Patients	Percentage(%)	No of Patients	Percentage(%)
1	36	90.00	37	92.50
2	4	10	3	7.5
3	0	0	0	0
TOTAL	40	100	40	100

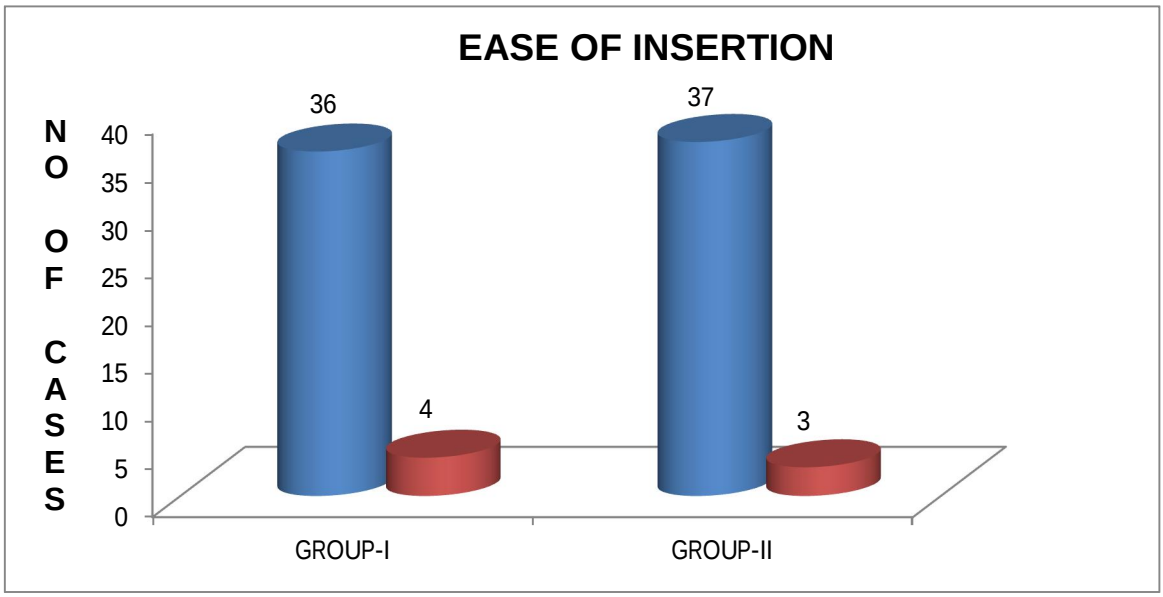

FIGURE 14

Easiness of insertion:

Out of total number of 80 patients, the insertion were very easy and easy in 73 and 7 cases respectively. 92.5% of the cases of group II had very easy insertion where as 90% cases of group-I had very easy insertion. This is evident from the table and charts .There were no cases of failure of LMA insertion in both the groups. The easiness of insertion of both devices was comparable and the difference was not significant statistically (p= 0.69)

TABLE - 10

NO OF ATTEMPT

No of Attempt	GROUP-I		GROUP-II	
	No of Patients	Percentage (%)	No of Patients	Percentage (%)
1	36	90	37	92.50
2	4	10	3	7.50
3	0	0	0	0
TOTAL	40	100	40	100

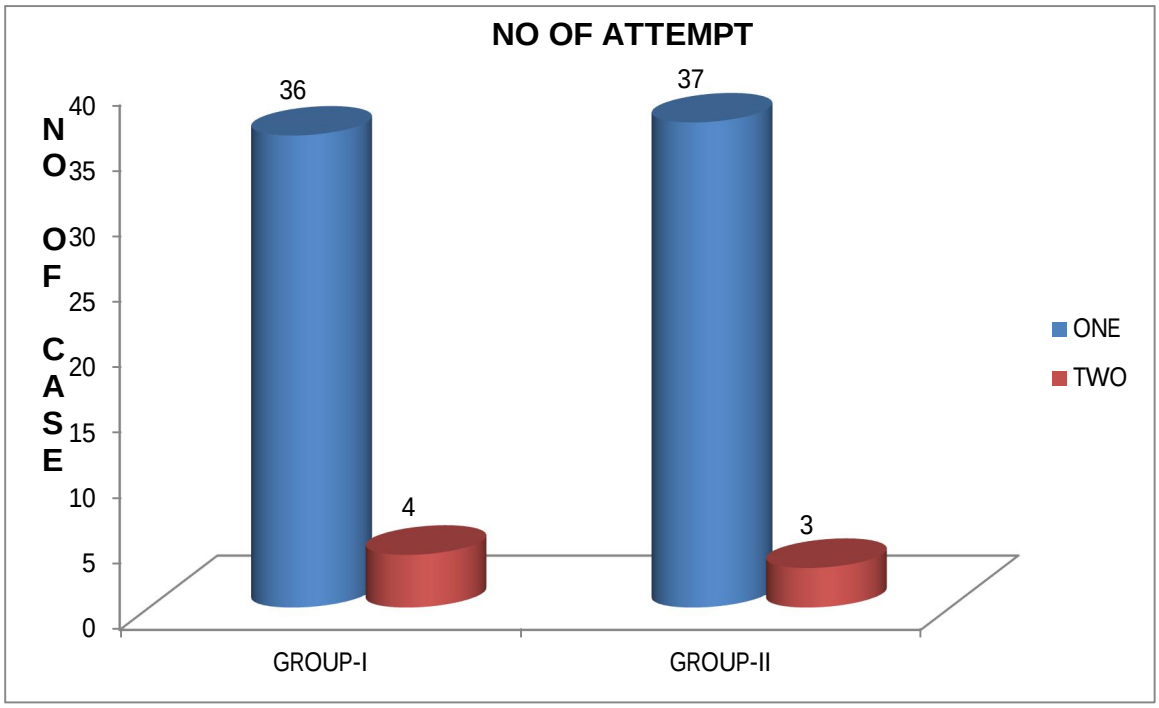

FIGURE 15

Number of Attempts :

Out of total number of 80 patients, the insertion was achieved in first attempt in 73 patients and second attempt was required only in 7 patients out of which 4 were for classic- LMA and 3 were for I-gel. The number of attempts required for insertion were also comparable and the difference were not significant statistically (p=0.69%)

TABLE - 11
TIME TAKEN FOR INSERTION

	Group I	Group II	P Value	Statistic significance
Mean time(sec)	**25.88±4.32**	**22.82±4.30**	**0.002**	**S**

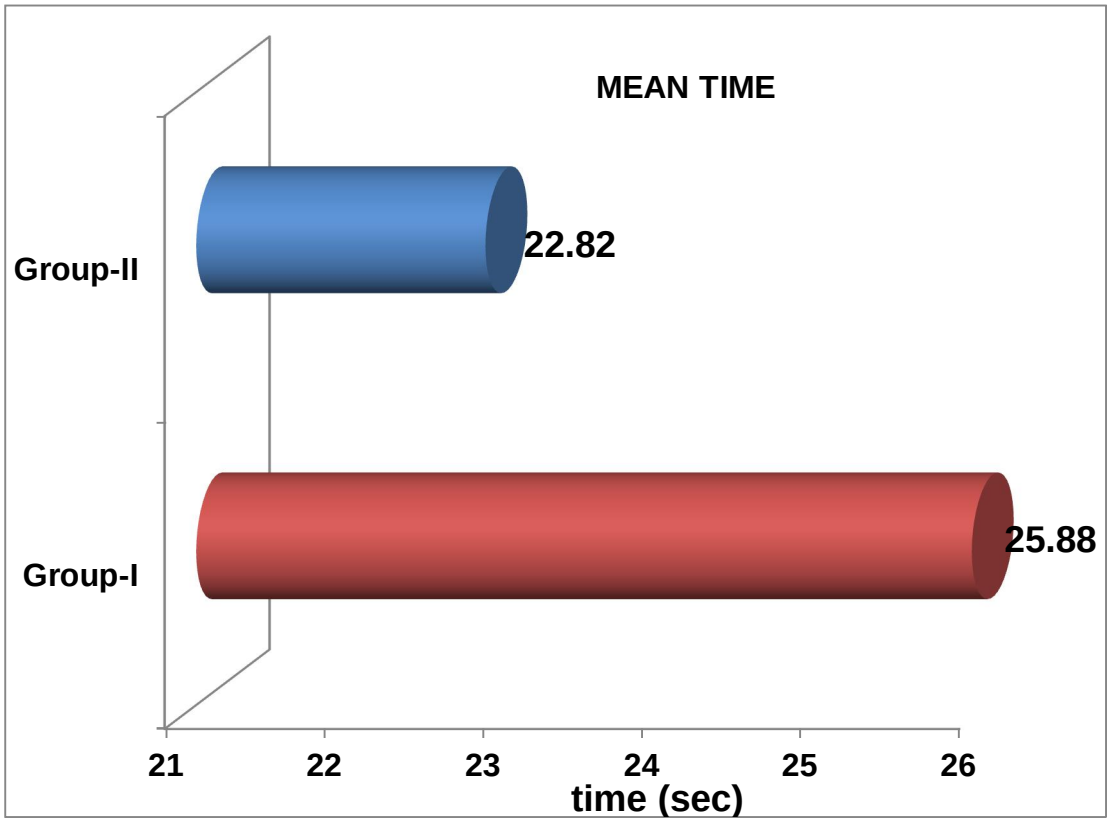

FIGURE:16

Time taken for insertion :

The mean time required for insertion of classic LMA was 25.88 seconds as against the mean time of 22.82 seconds required in case of I- gel. Time taken for insertion was also comparable and the p value was 0.002 and was statistically significant.

TABLE - 12
MEAN AIRWAY LEAK PRESSURE

	Group I	Group II	P Value	Statistical significance
Leak pressure(cmH_{2O})	**19.12±2.23**	**23.82±2.47**	**0.000**	**S**

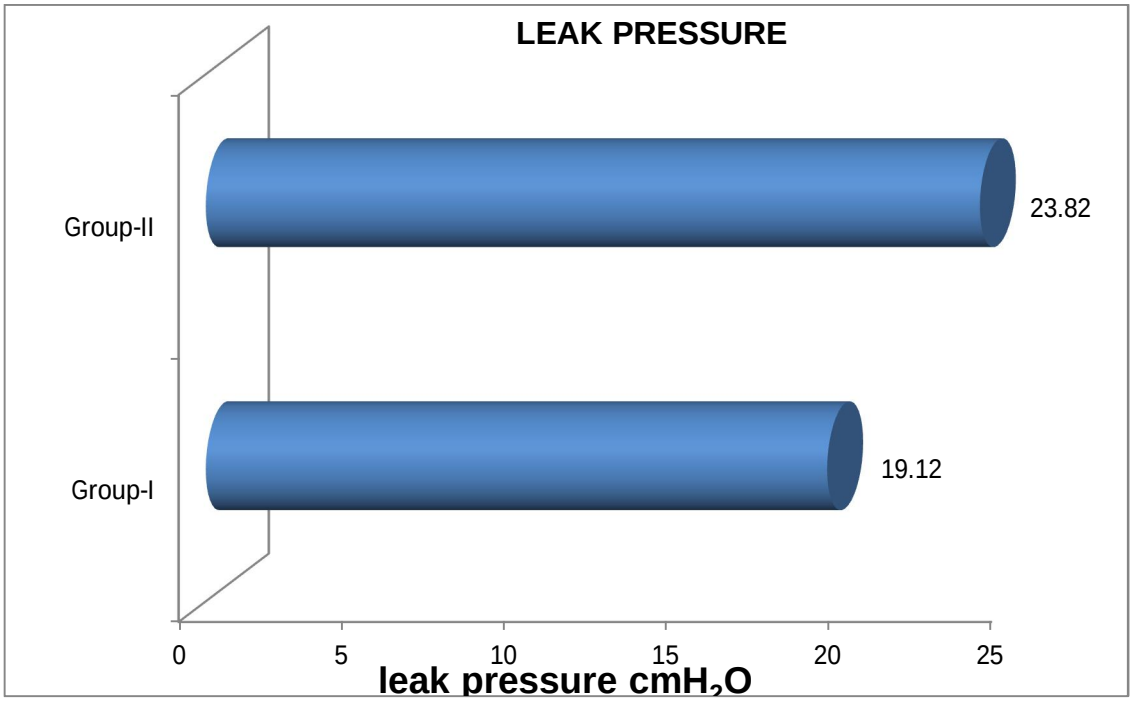

FIGURE 17

The mean airway leak pressure:

The mean airway leak pressure with I-gel in group 2 patients was 23.82±2.47 and with c-LMA in group 1 was19.12±2.23 cm H_2O and was highly significant statistically (p=0.000)

TABLE - 13

GASTRIC INSUFFLATION:

Gastric insufflation	GROUP-I		GROUP-II	
	No of Patients	Percentage(%)	No of Patients	Percentage(%)
YES	10	25.00	6	15.00
NO	30	75.00	34	85.00
TOTAL	40	100	40	100

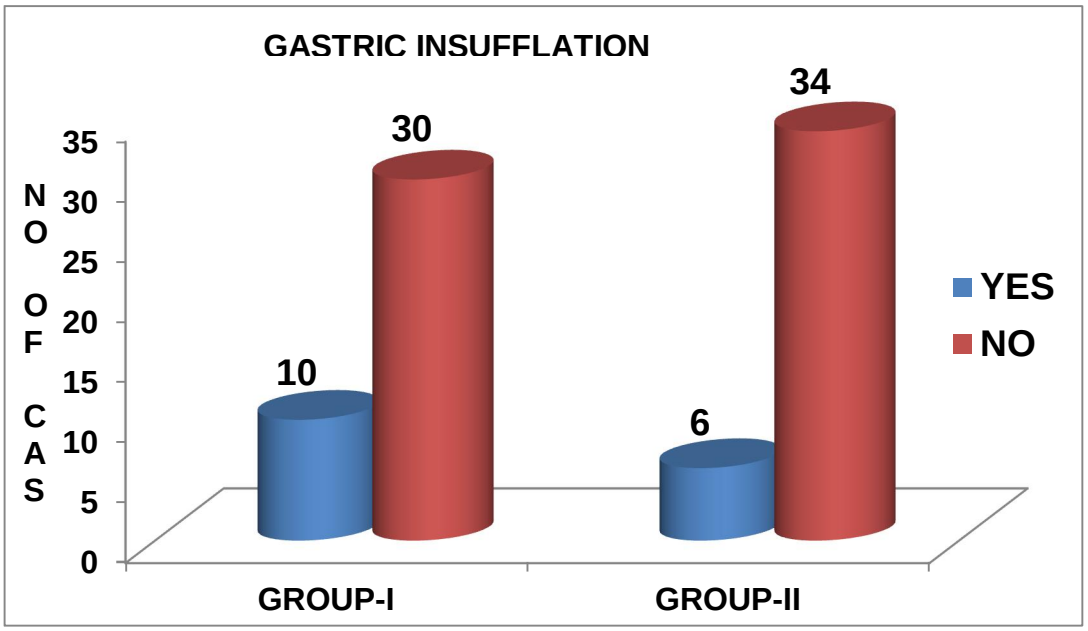

FIGURE: 18

The gastric insufflation:

Out of total number of 80 patients the gastric insufflation was not seen in 64 cases and was seen in only 16 cases out of which 10 were for classic LMA and 6 was for I-gel. The gastric insufflation was also comparable and the difference was not important statistically (p=0.26).

TABLE - 14

HEART RATE

Time intervals (Minutes)	GROUP-I		GROUP-II		t-value	p-value
	Mean	Sd	Mean	Sd		
Pre insertion	88.62	13.89	82.28	8.16	2.49	0.688
1min post insertion	89.58	15.64	83.75	11.85	1.89	0.591
5min post insertion	84.80	14.74	80.90	9.36	1.41	0.938

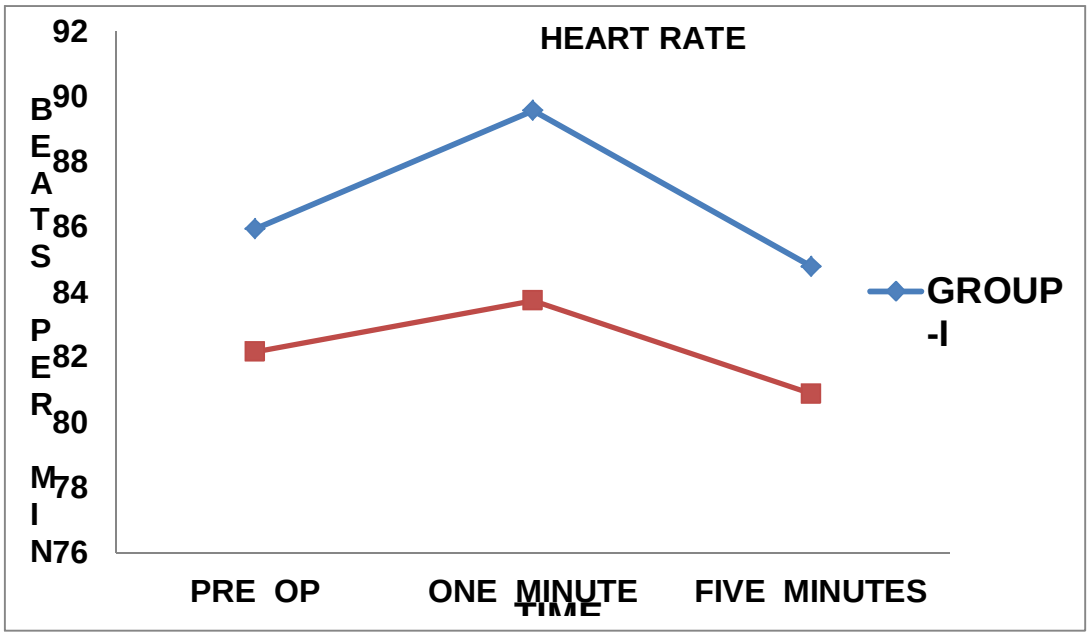

FIGURE:19

Hemodynamic parameters

Heart rate:

Comparison of pre insertion ,1 min post insertion ,and 5 min post insertion heart rate in group -I and group-II cases did not show any statistically significant difference as evident from the above table .

TABLE - 15
SYSTOLIC BLOOD PRESSURE

Time intervals (Minutes)	Group I		Group II		t-value	p-value
	Mean	Sd	Mean	Sd		
Pre insertion	122.12	10.70	122.75	10.20	0.27	0.79
1 min post insertion	121.62	7.71	123.88	6.96	0.58	0.56
5 min	118.52	1.01	118.65	2.12	0.05	0.96

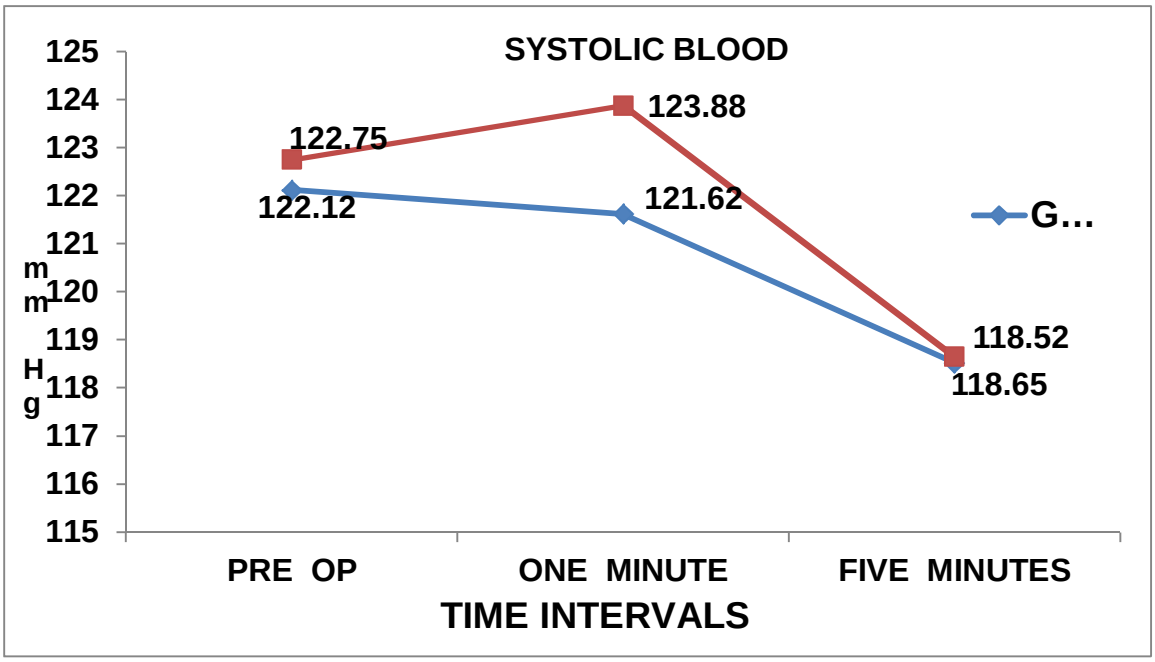

FIGURE: 20

Hemodynamic parameters

Systolic blood pressure

Comparison of pre insertion, 1 min post insertion ,and 5 min post insertion systolic blood pressure in group I and GROUP II cases did not show any statistically significant difference either.

TABLE - 16
DIASTOLIC BLOOD PRESSURE

Time intervals (Minutes)	Group-I		Group-II		t-value	p-value
	Mean	Sd	Mean	sd		
Pre insertion	77.72	7.66	77.00	8.54	0.40	0.69
1min post insertion	77.72	10.83	77.12	14.94	0.21	0.84
5min post insertion	72.98	8.18	74.42	17.63	0.49	0.63

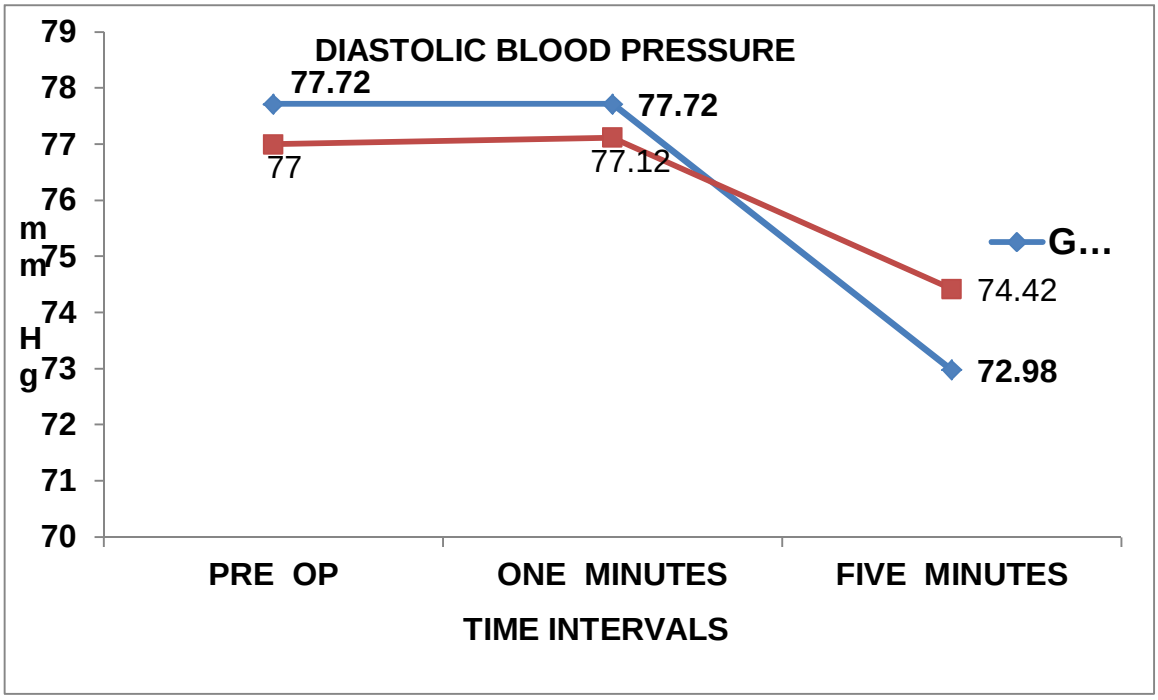

FIGURE: 21

Hemodynamic parameters

Diastolic blood pressure:

Comparison of pre insertion, 1 min post insertion, 5 min post insertion Diastolic blood pressure in classic LMA and I-gel cases had not showed any significant difference statistically.

All the above mentioned parameters (HR, SBP, DBP) were found to have marginal peak effect at 1 min post insertion in both the groups.

TABLE - 17

COMPLICATIONS

COMPLICATIONS	GROUP-I		GROUP-II	
	N	%	N	%
No Complications	23	57.5	29	72.5
Lip injury	5	12.5	1	2.50
Post removal cough	4	10.00	0	0
Postoperative nausea, vomiting	1	2.50	2	5.00
Dysphagia	0	0	2	5.00
Blood staining on airway device	7	17.50	6	15.00
Total	40	100	40	100

Out of total number of 80 cases, 52 cases did not have any complications at all. Out of 28 cases in which complications were observed. 17 cases had complication in group I, 11 cases had complications in group II.

6 cases had lip injury, 4 cases had post removal cough, 3 cases had nausea and vomiting, 2 cases had dysphagia. 13 cases had blood stain on airway device.

Out of the 6 cases of lip injury 5 cases were from group I and 1 case was from group II.

Out of 4 cases, with post removal cough on the LMA 4 were from group I.

Out of 3 cases with post of nausea and vomiting 1 was from group I while 2 were from group II.

Out of 13 cases of blood staining on airway 7 were from group I, while 6 were from group II.

None of the cases had laryngospasm, pulmonary edema during intra operative or post operative period. In terms of development of either intra op or post op complications, the difference between the two groups was not found to be statistically significant

DISCUSSION

DISCUSSION

This study was conducted in Institute of Obstetrics and Gynaecology (MMC, Chennai) between August 2014 to September 2014 and involved 80 patients in ASA I-II physical status. They were randomized in to 2 groups: Group –I-(Classical LMA) and Group –II (I–gel) and following parameters were analysed .

1) Ease of insertion
2) Number of attempts
3) Time of insertion
4) Airway Leak pressure
5) Gastric insufflation
6) Hemodynamic parameters
7) Airway injuries
8) Complications

Demographic criteria:

Both the groups are comparable and there is no statistically important difference regarding age, weight, body mass index.

Ease of insertion :

One of the primary objectives was to compare the ease of insertion between the two devices. The grading of insertion was done similar to the study conducted by Siddiqui et al.[28]

In our study, the ease of insertion of classic -LMA was very easy (score 1) in 36 (90%) patients and easy (score 2) only in 4 (10%) patient. In group 2 insertion of I -gel was score 1 and score 2 in 37(92.5%) and 3 (7.5%) patients respectively.

There is no statistically important difference between the two groups with respect to ease of insertion ($p>0.05$). The insertion of I-gel was found comparatively easier and required minimal skill as compared to Classical LMA. The group two device having a non inflatable cuff and firm in consistency was much easier for insertion as compared to LMA.

In our study the easiness of insertion of the device was compared with the study conducted by Ali A.[1] Siddiqui.[28] Janakiram.[15] who also did not find any statistically significant difference. Insertion of I-gel in our study was similar to Richez B et al.[26]study, who graded insertion of no-4 I-gel as very easy in 93% (66 of 71) patients and easy in remaining 7% (5 of 71) patients. Insertion of c-LMA in our study was comparable with Janakiram et al.[15] study where 90% (45 of 50) c-LMA insertions were easy insertions.

Number of attempts

TABLE – 18

Showing number of attempts of insertion in various study

Study-author and year	SAD	1st attempt insertion no. (%)	2nd attempt insertion no. (%)	3rd attempt insertion	p value
Uppal V et al.,[30] 2009	i-gel	38 (97.4%)	1 (2.6%)	-	
	c-LMA	39 (100%)	0%	-	
Janakiram et al.,[15] 2009	i-gel	27 (54%)	23 (46%)	-	
	c-LMA	43 (86%)	7 (14%)	-	0.001 (HS)
Franksen H et al.,[10] 2009	i-gel	36 (90%)	4 (10%)	-	
	c-LMA	34 (85%)	5 (13%)	-	-
Amini S et al.,[2] 2010	i-gel	48 (80%)	11 (18%)	-	
	c-LMA	46 (77%)	10 (17%)	-	0.73 (NS)
Helmy AM et al.,[13] 2010	i-gel	36 (90%)	4 (10%)	-	
	c-LMA	32 (80%)	6 (15%)	2 (5%)	-
Siddiqui AS et al.,[28]2010	i-gel	43 (86%)	7 (14%)	-	0.54(NS)
	c-LMA	45 (90%)	10%	-	
Present study	**i-gel**	**37(92.50)**	**3(7.50%)**	-	0.092 (NS)
	c-LMA	**36 (90%)**	**4(10%)**	-	

In this study, insertion of group 2 airway device was successful in 1st insertion in 92.50% cases as Compared to 90% first time insertion with c-LMA. Airway manipulation like jaw thrust was required during second attempt insertion

in 7.5% of patient of I-gel insertion and 10% patients with c-LMA insertions. Very similar results were found in studies conducted by Helmy AM et al.[13] Uppal V et al.[30] Franksen H.[10] Amini S .[2] Siddiqui AS .[30] as shown in table .

In Janakiram et al.[15] study, the success rate with first time I-gel insertion was only 54%, and with c-LMA of 86% which was statistically highly significant. This is because the author has used large size I-gel in 14 patients due to presence of audible leak and hence required second attempt. However, in our study we did not have such problem and comparable between both the devices.

Time of insertion

TABLE - 19 : Showing the time of insertion of SAD in various studies

Study-author and year		Time of insertion (seconds)	p value
Uppal V et al.,[30] 2009	I-gel	12.2 (9.7-14.3)	0.007 (HS)
	c-LMA	15.2 (13.2-17.3)	
Franksen H et al.,[4] 2009	I-gel	15 (10-60)	0.45 (NS)
	c-LMA	17 (11-180)	
Parul Jet al.,[25] 2009	I-gel	3.48±1.41	<0.05 (S)
	c-LMA	7.68±0.69	
Amini S et al.,[2] 2010	I-gel	20 (10.4-29.6)	>0.05 (NS)
	c-LMA	24.2 (11.6-36.8)	
Helmy AM et al.,[13] 2010	I-gel	15.62 (10.72-20.52)	0.0023 (HS)
	c-LMA	26.2 (8.5-43.9)	
Ali A et al., [1]2010	I-gel	10.76±5.17	0.92 (NS)
	c-LMA	10.90±5.53	
Present study	**I-gel**	22.82±4.30	0.002 (HS)
	c-LMA	25.88 ±4.32	

The time for insertion was considered according to the study conducted by Helmy AM et al.[13] from picking up the device to confirmation of effective

ventilation by bilateral chest movement, square wave pattern capnography, normal range end tidal CO_2 and stable arterial SpO_2 (>95%).[10,2]

In our study, the time for insertion of I-gel (22.82s) was shorter compared to Classic-LMA (25.88 s) which was highly significant statistically (p=0.002).

The I-gel Supraglottic airway device is made of thermoplastic elastomer and has no cuff to be inflated after its insertion, hence requires less time for successful insertion as compared to Classic-LMA which has a cuff to be inflated after its insertion.

Consistent with our results, Helmy AM et al.[13] Uppal V et al.[30] Parul J et al.[5] also had significant difference in the insertion times as shown in Table . In Franksen H et al.[10] Amini S et al.[2] Ali A et al.[1] studies, though the mean time for I-gel insertion was clinically shorter as compared to c-LMA, it was not statistically significant.

Airway leak pressure

TABLE - 20

Showing airway leak pressure in various studies

Study-author and year	**SAD**	**Airway leak pressure (cm H_2O)**	**p value**
Uppal Vet al.,[30] 2009	I-gel	25	0.084 (NS)
	c-LMA	22	
Janakiram et al.,[15] 2009	I-gel	20	0.023 (S)
	c-LMA	17	
Franksen H et al.,[10] 2009	I-gel	29	0.0001 (HS)
	c-LMA	20	
Amini S et al.,[2] 2010	I-gel	22.6	0.02 (S)
	c-LMA	19.3	
Helmy AM et al.,[13] 2010	I-gel	25.62	0.0016 (HS)
	c-LMA	21.2	
Present study	**I-gel**	23.82	0.002 (HS)
	c-LMA	19.12	

Airway leak pressure detection was performed in a similar manner done by Uppal V et al.[30] in their study. The difference in the oropharyngeal sealing pressure between group I and group II were statistically significant in our study (p=0.000)

similar to the previous studies of Janakiram .[15] Franksen H .[10] Amini S .[2] and Helmy AM .[13] as shown in the above table .

Airway leak pressure of I-gel in our study was comparable with Uppal V et al.[30] and Helmy AM et al.[13] studies and of c-LMA with Amini S et al.[2] study, as shown in Table.

Haemodynamic changes:

While inserting and removing the airway devices ,the hemodynamic changes are produced because of mechanical contact between device and oropharyngeal structures, pressure over the larynx and pharynx produced by inflated cuff and dome of airway device .[16]

The haemodynamic parameters were monitored in the following time interval – Basal before isertion,, 1 minute after insertion, 5 minutes after insertion .[16]

In our study, there was no important difference between two groups with regarding to all hemodynamic parameters. The results of our study were similar to the studies done by Helmy AM et al.[13] Franksen H et al.[15] who in their studies found no significant difference between two groups regard to all hemodynamic parameters. Jindal P et al.[16] in their study observed that I-gel produced less haemodynamic changes compared to other Supraglottic airway devices. Since I–

gel can change its shape according to temperature, At normal body temperature it correctly fits into perilaryngeal structures, does not produce much pressure over anatomical structures, hence produce less hemodynamic changes when compared to Classic-LMA which because of an inflatable cuff can produce more haemodynamic changes.

Injuries

The inflatable Supraglottic airway devices during insertion, the deflated leading edge of the mask can catch the epiglottis edge and cause it to down-fold or impede proper placement beneath the tongue and can cause pharyngeal injury.[35] Inflatable masks also have the potential to cause tissue distortion, venous compression and nerve injury.[23]

In our study, at the end of procedure, the patients were inspected for any trauma to oral cavity , which is similar to study done by Siddiqui AS et al.[28] Lip injury was noted in 5 patients in group I out of 40 and in 1 patient out of 40 in group II. However the incidence was not statistically significant. Similar results have been observed in studies done by Helmy AM et al.[13] In the study conducted by Siddiqui AS et al.,[28]blood on device was noted in 18% cases of LMA group while none in the I-gel group which was statistically significant. The authors

attributed the cause might be due to pressure produced by inflatable cup ,resulting in trauma to adjoining structures .

Postoperative complications

The patients were interviewed for any postoperative complications like sore throat, dysphagia and hoarseness after 18-24 hours.[2, 32]

Only 2 patients in group II had developed dysphagia post operatively compared to none in group I.

Our results were consistent with the studies done by Siddiqui AS et al.[28]

Helmy AM et al.[13]Fanksen H et al.[10] where the difference between two groups regarding postoperative morbidity was not statistically important. But there was higher incidence of nausea and vomiting in Classic–LMA group due to more incidence of gastric insufflation.[13]

Keijzer C et al.[18] in their study compared the post operative throat and neck complications between LMA and i-gel. They found there were more incidence of throat irritation and pain during swallowing at first hour, first day, and second day in the group I compared with the group II. And also more incidence of neck pain noted in c-LMA group. Since there is no cuff in I–gel, it causes less number of postoperative throat and neck pain.

SUMMARY

SUMMARY

A study entitled “Prospective, randomized, study to compare classic –LMA and I-gel in anaesthetised spontaneously breathing patients undergoing minor gynaecological surgeries”- was undertaken in Institute of Obstetrics and Gynaecology, Chennai, during the period of August 2014 to September 2014. The study was undertaken after obtaining ethical committee clearance as well as informed consent from all patients.

Eighty patients, scheduled for various elective minor gynaecological surgical procedures ,under general anaesthesia who meet the inclusion criteria were included in this study. The study population was randomly divided into two groups with 40 patients in each group.

Group I - Classic LMA (n=40)

Group II - I –gel (n=40)

Pre-anaesthetic evaluation was done on the evening before surgery. A routine pre-anaesthetic examination and routine investigations were done. On the day of surgery after recording the baseline readings, the patients were pre medicated with injection Midazolam 2 mg (iv), injection Fentanyl 1 mcg/kg. Then patients were preoxygenated with 100% oxygen for 3 minutes via a face mask with

closed circuit. Anaesthesia was induced with injection Propofol 2 mg/kg body weight. End point was loss of verbal communication and loss of eye-lash reflex. Modified muzi and colleagues scoring system was used to assess the tolerance of LMA insertion. Ideal score for LMA insertion is less than 2. Additional 0.5 mg/kg injection Propofol was given if the score was more than 2 or on any movement and after 3 minute the allotted device was inserted according to the manufacturer's instructions.

An effective airway was confirmed by bilateral symmetrical chest movement, square waveform on capnograph, normal range end tidal CO_2 and stable arterial SpO_2 (>95%). Device was secured with adhesive tape. Bite block was kept in case of LMA-classic and secured along with it with adhesive tape.

Anaesthesia was maintained using 66% nitrous oxide and 33% of oxygen with 1-2% Sevoflurane without any neuromuscular blocking agents .The patients was allowed to breath spontaneously. At the end of surgery the device was removed after they were fully awake and obeys commands . The patients were inspected for any injury of the lips, teeth or tongue and the device for blood staining. The patients were interviewed for any postoperative complications like sore throat, dysphagia and hoarseness 18-24 hours.

TABLE- 21

Showing the results obtained in the present study

	GROUP I	GROUP II
Mean age in years	38.60	39.35
Mean BMI	22.96	23.28
Ease of insertion(1/2/3)	36/4/0	37/3/0
Number of attempts (I/II)	36/4	37/3
Duration of insertion (seconds)	25.88	22.82
Airway leak pressure(cmH_2O)	19.12	23.82
Gastric insufflation(cases)	10	6
Lip injury(cases)	5	1
Blood on device(cases)	7	6
Post of sore throat(cases)	-	-
Post op dysphagia(cases)	0	2
Post op nausea ,vomiting(cases)	1	2

The insertion of I-gel was very easy in 37 patients and was easy in 3 patients. The insertion of c-LMA was very easy in 36 patients, and easy in 4 patients .The first time insertion rate was more with I-gel as compared to c-LMA. Airway manipulation like jaw thrust was required in 4 patients of c-LMA group.

The mean duration of insertion was significantly lower with I-gel than with c-LMA. The mean airway leak pressure was more with I-gel compared to c-LMA.

Both devices are easy to insert. There was no significant haemodynamic changes between I-gel and c-LMA with respect to heart rate, blood pressure and arterial oxygen saturation (SpO_2).

Postoperative complications were not significantly different between I-gel and Classic-LMA. The I-gel provides a better airway sealing pressure compared to c-LMA.

CONCLUSION

CONCLUSION

Both classic LMA and I-gel can be used safely and effectively during general anaesthesia with spontaneous breathing in selected patients. Both classic-LMA and I-gel did not cause any significant alterations in the hemodynamic status of patients. Both the devices were easy to insert. **But insertion of I-gel was easier and more rapid than insertion of Classic–LMA. Leak pressure was significantly higher with I-gel than with Classic-LMA. I-gel has low pharyngeolaryngeal morbidity rate as compared to Classic LMA.**

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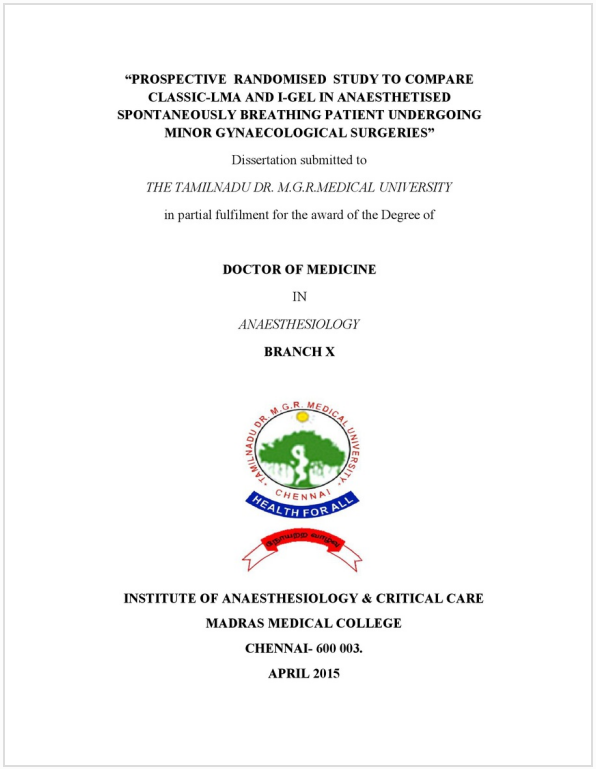

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APRIL 2015

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. A. Rajendran,
Postgraduate MD (Anaesthesia),
Madras Medical College,
Chennai – 600 003.

Dear Dr. A. Rajendran,

The Institutional Ethics Committee has considered your request and approved your study titled **"A Prospective randomized study to compare I-gel and classic LMA in anaesthetized spontaneously breathing patient undergoing minor gynaecological surgeries" No.**46082014.

The following members of Ethics Committee were present in the meeting held on 05.08.2014 conducted at Madras Medical College, Chennai-3.

1.	Dr.C.Rajendran, M.D.,	: Chairperson
2.	Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3.	Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4.	Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC	: Member
5.	Dr.G.Muralidharan, Director Incharge, Inst.of Surgery	: Member
6.	Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC	: Member
7.	Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
8.	Prof.Tito, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
9.	Thiru S.Rameshkumar, Administrative Officer	: Lay Person
10.	Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
11.	Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

MADRAS MEDICAL COLLEGE * CHENNAI-600 003 *
6 AUG 2014

Member Secretary, Ethics Committee

COMPARATIVE STUDY BETWEEN I-GEL

AND CLASSICAL LMA

Date: Roll No: Airway Device:

Name: Age: Sex: IP No:

Diagnosis: Surgical Procedure:

Ht: CVS: Hemoglobin:

Wt: RS: Blood Sugar:

BMI: Blood urea :

Creatinine:

Airway: MPC:

Pre OP Assessment: I/II

H/o.Any Co/morbid Illness:

H/o.Documented difficult airway, Previous surgery, Drug Allergy, Latex Allergy, H/o. Obstructive Sleep Apnea.

Duration of Surgery

Start Time: End Time: Total Duration:

MEASURES OF STUDY OUTCOME

1. Ease of Insertion : very easy / easy/ Difficult
2. Number of Attempts :
3. Time Taken for Insertion :
4. Leak Pressure :
5. Gastric insufflation :

6. VITALS: HR SBP DBP PO2 ETCO2

Pre insertion of device

Post insertion of device

1 min

5 min

7. Complications

Post Extubation Cough :

Breathing Holding :

Blood I-gel/ LMA :

Lip and Dental Injury :

Sore Throat		
Dysphagia		
Dysphonia		
Numbness of Tongue/ Oropharynx		
Blocked or painful ears		
Reduced hearing		
Neck Pain		

PATIENT CONSENT FORM

Study title : "**Prospective, randomized study comparing Classic LMA and I-gel in anaesthetised spontaneously breathing patients undergoing minor gynaecological surgeries"**

Study centre : Department of Anaesthesiology,
Institute of Obstetrics and Gynecology
Rajiv Gandhi Govt. Hospital, Egmore, Chennai.

Participant name : Age: Sex:
I.P.No:

I confirm that i have understood the purpose of procedure for the above study. I have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my participation in the study is voluntary and that i am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my health records both in respect to current study and any further research that may be conducted in relation to it, even if i withdraw from the study. I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. All results from the above study will be kept confidentially. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: Signature / thumb impression of patient

Place: Patient name:

Signature of the investigator:
Name of the investigator: A.Rajendran

INFORMATION TO PARTICIPANTS

Investigator : Dr.A.Rajendran

Name of the participants :

Title : "A prospective, randomized study comparing Classic LMA and I-gel in anaesthetised spontaneously breathing patients undergoing minor gynaecological surgeries"

You are invited to take part in this research study. We have got approval from the IEC. You are asked to participate because you satisfy the eligibility criteria. We want to compare and study the safety and efficacy of

What is the purpose of the research :

LMA is emerging as a replacement for endotracheal tube for giving general anaesthesia. This study compares the I-gel and classical LMA in terms of OSP, hemodynamic parameters and complications assess which LMA gives a better fit around the larynx**.**

The study design:

All the patients in the study will be divided into two groups randomly and will be premedicated. General anaesthesia will be induced with midazolam, fentanyl and propofol. First group will have classic LMA insertion. Second group will have I-gel insertion. The ease,time,number of attempts of insertion of the LMA will be noted. After this the OSP will be measured by closing the APL valve and keeping the flowrate at 3 liters per min and noting the airway pressure at which an audible leak can be heard (not exceeding 40cm of H_2O at cuff pressure of 60cm of H_2O). At the end of the operation anaesthetic agents will be discontinued, allowing smooth recovery of consciousness. The devices will be removed after you have regained consciousness and respond to verbal command. complications if any will be noted and treated. All results of this study will be kept confidentially.

Benefits:

This study will help us in deciding which LMA is best suited for giving general anaesthesia from functional as well as anatomical aspects**.**

Discomforts and risks:

Post op sore throat, cough, hoarseness of voice, laryngospasm have been reported in previous studies but can be managed effectively. Post op nausea and vomiting can be prevented by giving antiemetic inj.metoclopromide 10 mg half an hour before surgery.

Time:
Place:
Date:

Signature of investigator
Name: Dr.A.Rajendran

Signature of participant/
Thumb Impression
Name:

MASTER CHART

MPC	-	Mallampati grading
WT	-	Weight in kg
HT	-	Height in cm
BMI	-	Body mass index
Surg	-	Name of surgery
Gas	-	Gastric insufflation
FRA CURR	-	Fractional curettage
Aub	-	Abnormal uterine bleeding
Dub	-	Dysfunctional bleeding
EUA	-	Evaluation under anesthesia
S&E	-	Suction and Evacuation
The Cur	-	Therapeutic curettage

S NO	NAME	AGE	ASA	MPC	WT(KG)	HT(CM)	BMI	DIAGNOSIS	SURGERY	SAD	SIZE	EASINESS OF INSERTION	NO. OF ATTEMPT	TIME IN SECONDS	LEAK PRESSURE	GASTRIC INSUFFLATION	COMPLICATIONS	PRE INSERTION HR	PRE INSERTION SBP	PRE INSERTION DBP	POST INSERTION 1 MINT HR	POST INSERTION 1 MIN SBP	POST INSERTION 1 MIN DBP	POSRT INSERTION 5 MIN HR	POST INSERTION 5 MIN SBP	POST INSERTION 5 MIN DBP
1	KALAIVANI	22	I	II	58	155	24.1	WOUND GAPE	2NDRY SUTURING	IGEL	4	1	1	30	28	NO	1	82	118	76	88	135	93	90	124	74
2	MURUGAMMAL	50	I	I	58	154	24.1	DUB	FRA-CUR	IGEL	4	2	2	30	23	NO	-	80	132	65	91	120	60	86	134	80
3	DHILSAD	45	I	II	55	154	23.2	DUB	FRA-CUR	IGEL	4	1	1	20	25	NO	-	78	117	89	74	120	78	80	118	66
4	VIJAYALAKSHMKI	45	I	I	50	150	22.2	DUB	FRA-CUR	IGEL	3	1	1	18	22	NO	-	86	133	74	90	140	68	76	123	73
5	DATCHAYANI	49	I	II	45	145	21.4	FIBROID	FRA-CUR	IGEL	3	2	2	26	25	YES	-	70	110	72	68	100	60	86	108	62
6	SUNITHA	43	I	I	53	151	23.2	DUB	FRA-CUR	IGEL	4	1	1	30	30	NO	5	67	131	80	64	105	59	62	106	59
7	VASANTHI	45	I	I	58	155	24.1	AUB	FRA-CUR	IGEL	4	1	1	28	28	NO	-	70	131	75	66	105	73	60	115	84
8	RANI	48	I	I	53	150	23.55	AUB	FRA-CUR	IGEL	4	1	1	30	26	NO	-	92	133	90	98	154	94	88	142	82
9	DEVI	30	II	II	62	156	24.4	WOUND GAPE	2NDRY SU	IGEL	4	1	1	24	26	NO	-	84	108	66	78	97	74	68	112	80
10	SELVI	48	I	II	54	155	22.5	CERVICAL POLYP	POLYPECTOMY	IGEL	3	1	1	24	26	YES	-	70	119	66	66	105	57	63	101	51
11	GOVINDAMMAL	45	I	I	53	150	23.55	FIBROID	FRA-CUR	IGEL	3	1	1	22	24	NO	5	86	118	84	72	112	80	84	120	85
12	ZULAIKHA	24	I	I	45	145	21.42	WOUND GAPE	2NDRY SU	IGEL	3	1	1	24	24	NO	-	86	123	67	72	100	52	70	107	50
13	THANGAM	26	I	II	56	150	24.8	WOUND GAPE	2NDRY SU	IGEL	4	1	1	22	26	NO	-	90	133	73	94	144	101	100	132	80
14	UMA	24	I	I	52	152	22.41	MISSED ABORTION	S&E	IGEL	3	1	1	20	22	NO	-	86	117	75	78	99	50	76	112	155
15	THANGAMMAL	48	II	I	55	153	23.1	PMB	FRA-CUR	IGEL	4	1	1	22	22	NO	-	86	119	66	76	105	57	72	101	51
16	BANU R	40	I	I	60	155	25	AUB	FRA-CUR	IGEL	4	1	1	18	24	NO	2	83	100	62	70	97	52	72	95	58
17	BADMINI	47	I	II	53	150	23.5	DUB	FRA-CUR	IGEL	3	1	1	18	20	NO	5	86	137	70	68	128	68	70	110	70
18	SELVI BASKAR	44	I	I	65	163	24.5	PMB	FRA-CUR	IGEL	4	1	1	20	22	NO	-	86	138	61	84	116	61	80	102	46
19	DASAMMAL	37	I	I	52	150	23.1	AUB	FRA-CUR	IGEL	3	1	1	18	22	YES	2	82	130	90	98	148	96	90	133	90
20	PRIYA	23	I	I	40	134	22.3	WOUND GAPE	2NDRY SU	IGEL	3	1	1	20	22	NO	-	86	113	72	80	100	58	82	102	58
21	ANANTHI	40	I	I	60	160	23.4	AUB	FRA-CUR	IGEL	4	2	2	30	22	NO	-	92	131	91	86	123	88	80	115	79
22	KANAGA	46	I	II	60	160	23.4	DUB	FRA-CUR	IGEL	4	1	1	18	22	YES	3	60	118	76	71	108	72	68	102	70
23	CHINTHAMMAL	39	I	II	50	150	22.2	CERVICAL POLYP	POLYPECTOMY	IGEL	3	2	2	35	22	NO	-	86	120	76	102	140	90	84	118	80
24	VALARMATHI	40	II	II	60	160	23.4	DUB	FRA-CUR	IGEL	4	1	1	18	25	NO	5	92	130	80	110	140	80	96	130	70
25	DEEPTHI	28	I	II	60	155	25	WOUND GAPE	2NDRY SU	IGEL	4	1	1	18	20	NO	-	86	110	70	92	108	68	82	110	60
26	PUSPHALATHA	43	I	II	60	155	25	ENDO MET HYPERPLASIA	FRA-CUR	IGEL	4	1	1	18	24	YES	3	76	130	80	96	140	70	80	130	70
27	RAJESHWARI	31	I	I	49	149	22.1	FIBROID	FRA-CUR	IGEL	3	1	1	22	25	NO	-	89	110	70	96	133	90	94	129	72
28	MEGALA	46	I	I	52	155	21.6	FIBROID	FRA-CUR	IGEL	4	1	1	22	25	NO	-	92	126	84	98	132	95	86	144	100
29	RADHIKA	45	II	II	60	157	24.3	AUB	FRA-CUR	IGEL	4	1	1	20	25	NO	-	84	118	76	82	126	74	80	124	80
30	NESAMANI	35	II	I	56	152	24.2	AUB	FRA-CUR	IGEL	4	1	1	23	24	YES	-	78	117	89	74	120	78	80	118	66
31	JAMUNA	31	I	I	55	154	23.2	WOUND GAPE	2NDRY SU	IGEL	4	1	1	20	26	NO	-	86	126	88	92	139	94	84	118	76
32	GOVINDAMMAL	35	II	II	60	159	23.7	FIBROID	FRA-CUR	IGEL	4	1	1	20	24	NO	-	82	118	76	88	135	93	90	124	74
33	JOTHI	40	I	II	45	140	23	AUB	FRA-CUR	IGEL	3	1	1	22	26	NO	-	94	126	78	97	136	90	88	110	70
34	SAROJA	35	I	I	46	140	23.5	AUB	FRA-CUR	IGEL	3	1	1	22	26	NO	-	82	110	76	89	122	80	90	122	84
35	GOVINDAMMAL	50	I	I	46	146	21.6	PMB	EUA	IGEL	3	1	1	24	23	NO	5	64	150	90	66	152	92	72	140	88
36	SRIMATHI	44	I	I	45	142	22.3	AUB	FRA-CUR	IGEL	3	1	1	25	17	NO	1	78	117	88	84	133	96	85	122	78
37	PARVATHI	57	II	II	58	159	22.9	AUB	FRA-CUR	IGEL	4	1	1	24	24	NO	-	72	122	82	80	136	90	82	126	80
38	KALAIVANI	46	I	II	55	154	23.2	FIBROID	FRA-CUR	IGEL	4	1	1	26	20	NO	-	88	110	70	90	125	76	84	115	74
39	SHANMUGAPRIYA	24	II	I	52	151	22.8	WOUND GAPE	2NDRY SU	IGEL	4	1	1	22	23	NO	-	84	126	82	94	132	88	90	122	82
40	POONGODI	36	I	I	58	155	24.1	FIBROID	FRA-CUR	IGEL	4	1	1	20	23	NO	-	90	135	85	88	145	90	86	130	70

S. No	NAME	AGE	ASA	MPC	WT(KG)	HT(CM)	BMI	DIAGNOSIS	SURGERY	SAD	SIZE	EASINESS OF INSERTION	NO. OF ATTEMPT	TIME IN SECONDS	LEAK PRESSURE	GASTRIC INSUFFLATION	COMPLICATIONS	PRE INSERTION HR	PRE INSERTION SBP	PRE INSERTION DBP	POST INSERTION 1 MINT HR	POST INSERTION 1 MIN SBP	POST INSERTION 1 MIN DBP	POSRT INSERTION 5 MIN HR	POST INSERTION 5 MIN SBP	POST INSERTION 5 MIN DBP
1	GOVINDAMMAL	38	I	II	50	142	24.8	DUB	FRA-CUR	CLMA	3	1	1	26	18	NO		86	126	88	92	139	94	84	118	76
2	MALAR	48	I	II	50	150	22.2	PMB	FRA-CUR	CLMA	3	1	1	28	19	NO	-	94	126	78	97	136	90	88	110	70
3	GEETHA	26	I	II	60	159	23..7	MISSED ABORTION	THE CUR	CLMA	4	1	1	26	18	NO	-	82	100	70	92	118	80	96	120	74
4	SOFRABEE	53	II	II	48	142	23.8	DUB	FRA-CUR	CLMA	3	2	2	36	21	NO	-	66	145	90	64	118	75	58	140	80
5	BAGYALAKSHMI	26	I	II	56	152	24.2	MISSED ABORTION	THE CUR	CLMA	4	1	1	25	23	NO	-	80	124	76	66	132	70	60	128	70
6	RENUKA	26	I	II	55	154	22	WOUND GAP	SECONDRY SUTURING	CLMA	4	1	1	26	23	NO	5	66	127	99	74	106	71	60	115	77
7	THIMI	48	I	I	52	151	22.8	AUB	FRA-CUR	CLMA	4	1	1	30	20	NO	-	91	133	87	66	105	73	60	115	75
8	RAJESWARI	45	I	I	56	154	23.62	AUB	FRA-CUR	CLMA	4	1	1	34	20	YES	3	80	126	78	102	145	82	83	132	82
9	NITHYA	23	I	I	52	149	23.63	MISSED ABORTION	THE CUR	CLMA	3	1	1	36	18	NO	-	82	111	76	96	132	96	85	133	95
10	VATCHALA	48	I	I	53	151	23.2	DUB	THE CUR	CLMA	4	1	1	28	22	YES	1	70	128	65	66	119	77	66	115	75
11	RANI RAJESH	45	I	I	56	156	23.04	PMB	FRA-CUR	CLMA	4	1	1	25	18	NO	-	115	133	73	96	144	93	80	132	80
12	ANDAL	51	I	I	56	154	23.62	PMB	EUA, CX BIOPSY	CLMA	4	1	1	26	28	YES	5	110	110	70	98	90	56	96	111	68
13	SRIMATHI	43	I	I	52	149	23.63	FIBROID	FRA-CUR	CLMA	3	1	1	28	18	NO	-	67	114	69	82	112	69	77	98	61
14	JOTHI	29	I	I	52	157	21.1	VESI MOLE	S&E	CLMA	3	1	1	26	19	NO	1	86	119	66	76	105	57	72	101	51
15	VIJAYALAKSHMI	48	I	I	54	160	21.09	PMB	FRA-CUR	CLMA	4	1	1	26	18	NO	-	86	126	78	95	155	94	88	144	86
16	KALAIVANI	24	I	I	55	155	22.9	WOUND GAP	SECONDRY SUTURING	CLMA	4	1	1	28	18	YES	5	96	118	78	82	102	64	80	112	68
17	SELVI	38	I	I	60	160	23.4	WOUND GAP	SECONDRY SUTURING	CLMA	4	1	1	28	18	NO	-	102	115	69	91	101	68	92	114	75
18	MUTHUMANI	21	I	I	50	146	23	MISS ABORT	S&E	CLMA	3	1	1	24	19	YES	-	75	132	87	70	116	78	68	110	70
19	KUPPABAI	38	II	I	60	163	22.64	DUB	FRA-CUR	CLMA	4	1	1	26	19	NO	2	86	133	83	80	122	77	80	104	61
20	SELVI	33	I	I	60	163	22.64	WOUND GAP	SECONDRY SUTURING	CLMA	4	1	1	24	17	NO	-	88	132	87	80	116	78	82	110	70
21	NIRMALA	40	I	I	55	153	23.1	FIBROID	FRA-CUR	CLMA	4	1	1	25	18	NO	-	92	126	80	88	100	60	89	120	76
22	NITHYA	23	I	I	55	154	22	MISS ABORT	S&E	CLMA	4	1	1	24	18	YES	5	96	120	84	80	90	60	84	124	70
23	KALPANA	23	I	I	55	160	21.48	MISS ABORT	S&E	CLMA	4	1	1	26	19	NO	1	115	118	65	102	153	95	98	105	63
24	JAMILA	43	I	II	45	140	23	CERVICAL POLYP	POLYPECTOMY	CLMA	3	2	2	30	22	YES	-	73	112	77	60	117	83	60	108	74
25	SUSILA	45	I	I	50	147	23.14	DUB	FRA-CUR	CLMA	3	1	1	22	19	YES	2	86	127	76	80	98	76	78	95	60
26	SELVI	43	I	I	56	156	23	DUB	FRA-CUR	CLMA	4	1	1	28	20	NO	-	75	144	76	80	97	70	86	115	80
27	KUPPAMMAL	40	I	I	55	155	22.9	DUB	FRA-CUR	CLMA	4	1	1	25	18	NO	-	92	120	80	104	140	80	90	130	76
28	RUJULA	35	II	II	55	155	22.9	DUB	FRA-CUR	CLMA	4	1	1	20	18	NO	5	96	120	82	110	100	72	98	110	66
29	SEETHA	26	I	II	50	150	22.2	INCOMPLETE ABORTION	S&E	CLMA	4	1	1	20	18	NO	-	86	120	72	96	140	80	92	130	70
30	MALAR SELVI	46	I	I	60	156	24.6	AUB	FRA-CUR	CLMA	4	1	1	22	17	NO	1	92	130	80	108	140	86	90	120	80
31	RADHA	55	I	II	45	145	21.5	PMB	FRA-CUR	CLMA	3	1	1	24	20	NO	-	80	130	80	88	120	70	84	110	70
32	RANI	55	I	II	50	147	23.1	FIBROID	FRA-CUR	CLMA	4	1	1	20	19	NO	2	73	106	86	88	133	72	84	122	68
33	AMSA	35	II	II	60	159	23.7	FIBROID	FRA-CUR	CLMA	4	1	1	25	17	NO	-	82	118	76	88	135	93	90	124	74
34	NITHYA	45	II	II	49	152	21.2	PMB	FRA-CUR	CLMA	3	1	1	25	16	YES	-	89	108	70	94	118	74	90	126	72
35	KANIMOZHI	48	I	II	50	150	22.2	FIBROID	FRA-CUR	CLMA	3	1	1	22	18	NO	-	78	116	70	84	132	74	86	120	86
36	MALAR	39	I	I	48	141	24.24	AUB	FRA-CUR	CLMA	3	1	1	24	20	NO	5	92	110	70	104	112	74	90	120	72
37	SAROJA	45	II	II	50	150	22.2	AUB	FRA-CUR	CLMA	3	1	1	22	19	YES	1	110	100	70	114	118	80	108	120	74
38	JAYARANI	36	II	II	58	155	24.1	FIBROID	FRA-CUR	CLMA	4	1	1	16	15	NO	2	116	135	85	124	145	90	122	129	68
39	SHANTHI RANI	35	I	II	47	144	22.7	AUB	FRA-CUR	CLMA	3	2	2	36	19	NO	-	98	112	78	102	124	88	96	122	86
40	LAKSHMI	36	I	I	58	155	24.1	FIBROID	FRA-CUR	CLMA	4	1	1	23	21	NO	5	116	135	85	124	140	90	122	129	68